Management of Obstructive Sleep Apnea
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Sleep Evaluation in Newly Discovered OSA In and After Hospital

Clete A. Kushida, M.D., Ph.D.

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Medical Director, Stanford Sleep Medicine Center
Director, Stanford Center for Human Sleep Research

- Sleep evaluation in newly discovered OSA in patients during hospitalization
- Sleep evaluation in newly discovered OSA in patients after hospitalization
- Management of OSA in patients during and after hospitalization
- What about the future?
  - Prevalence of OSA in patients with chronic medical conditions
  - What evidence-based tools can be used to evaluate OSA in hospitalized patients?
  - What else can improve the pretest probability for detecting OSA in hospitalized patients?

Alzheimer's Disease: OSA

OSA is found in 33-53% of patients with probable Alzheimer's Disease

APOE4 genotype: Risk factor for SDB in the middle-aged Wisconsin Sleep Cohort Study,[1] but not in the elderly Honolulu-Asian Study cohort[2]

(1) Kadotani H, et al, JAMA 2001; (2) Foley DJ, et al JAMA 2001

Stroke

- Stroke can result in SDB, including central and obstructive apnea and disorders of respiratory control.
- SDB is the most commonly reported disturbance post- stroke, although adults are observed to have a high incidence of periodic breathing and Cheyne-Stokes respiration.
- Patients post stroke have a high OSA prevalence (60-93%). In a meta-analysis of 2343 subjects with ischemic or hemorrhagic stroke or TIA, OSA was present in 72%, with only 7% due to central apnea.

Johnson KG, et al. J Clin Sleep Med. 2010;6(2):138-9

Cardiovascular Disease

- About 50% of OSA patients are hypertensive, and an estimated 30% of hypertensive patients also have OSA, often undiagnosed.
- OSA was detected in 37% of 450 and 11% of 81 patients with heart failure resulting from systolic dysfunction referred for polysomnography.
- OSA in patients with CAD ranges from 26% to 66%, partially explained by the different AHI cutoff scores.

Silverberg DS, Sleep-related breathing disorders as a major cause of essential hypertension: fact or fiction?. Curr Opin Nephrol Hypertens. 7:1998:353-357. Fletcher EC, Undiagnosed sleep apnea in patients with essential hypertension. Ann Intern Med. 103 1985:190-195. Sin DD, Risk factors for central and obstructive sleep apnea in 450 men and women with congestive heart failure. Am J Respir Crit Care Med. 160 1999:1101-1106. Javaheri S, Sleep apnea in 81 ambulatory male patients with stable heart failure. Types and their prevalences, consequences, and presentations. Circulation. 97 1998:2154-2159. Somers V, Sleep apnea and cardiovascular disease. J Am Coll Cardiol. 2008;52(8):686-717.

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Pre-Test Probability for Moderate to Severe OSA

- to predict OSA (AHI ≥ 15 or ≥ 30 events/hour: 93 and 100%, respectively).[1]
- "The strength of evidence is low that some clinical prediction rules may be useful in the prediction of a diagnosis of OSA." [1]
- Age, sex, body mass index, bed partner observation of apnea and pharyngeal examination can be significant predictors of AHI. [2]
- Trained and experienced sleep physicians are best suited to evaluate and treat OSA patients.

(1) Hoffstein V, Szalai JP. Predictive value of clinical features in diagnosing obstructive sleep apnea. Sleep. 1993 Feb;16(2):118-22.
(2) Balk EM, et al.. Diagnosis and Treatment of Obstructive Sleep Apnea in Adults. Comparative Effectiveness Review No. 32. AHRQ Publication No. 11-EHC052-EF. Rockville, MD: Agency for Healthcare Research and Quality, 2011.

Questionnaires vs. PSG

Study PMID	Index test	Reference test	N	Setting	Bland-Altman		ROC Analysis					Quality
					Metric[4]	Result	Threshold, events/hr Index	PSG	Sensitivity (95% CI)	Specificity (95% CI)	AUC	
Chung, 2008[96] 18431116	STOP	PSG	177	Sleep lab			High vs. low	>5	65.5 (56.4, 73.9)	60 (45.9, 73.0)	0.703	C
								>15	74.3 (62.4, 84.0)	53.3 (43.4, 63.0)	0.722	
								>30	79.5 (63.5, 90.7)	48.6 (40.0, 63.0)	0.769	
	STOP-Bang						High vs. low	>5	83.6 (75.8, 89.7)	56.4 (42.3, 69.7)	0.806	
								>15	92.9 (84.1, 97.6)	43 (33.5, 52.9)	0.782	
								>30	100 (91.0, 100.0)	37 (28.9, 45.6)	0.822	
Chung, 2008[97] 18431117	Berlin	PSG	211	Sleep lab			High vs. low	>5	68.9 (59.8, 76.9)	56.4 (42.3, 69.7)	0.69	C
								>15	78.6 (67.1, 87.5)	50.5 (40.6, 62.3)	0.672	
								>30	87.2 (72.6, 95.7)	46.4 (37.9, 55.1)	0.668	
	ASA checklist						High vs. low	>5	72.1 (63.3, 79.9)	38.2 (25.4, 52.3)	0.783	
								>15	78.6 (67.1, 87.5)	37.4 (28.2, 47.3)	0.73	
								>30	87.2 (72.6, 95.7)	36.2 (28.2, 44.8)	0.617	
Kapuniai, 1988[98] 3227223	Apnea score derived from the Hawaii Sleep Questionnaire *	PSG	53	Sleep lab			≥3	>5	59 (nd)	69 (nd)		B
							≥2 (no adenoidectomy score)	>5	70 (nd)	65 (nd)		
							≥2 (no adenoidectomy score)	>10	78 (nd)	67 (nd)		
Netzer, 1999[99] 10507956	Berlin	PSG	100	Home			High-risk (high risk in 2/3 categories) vs. low-risk †	≤ 5	77 (nd)	89 (nd)		C
								>5	86 (nd)	77 (nd)		
								>15	54 (nd)	97 (nd)		
								>30	17 (nd)	97 (nd)		
Sharma, 2006[100] 17085831	Berlin Questionnaire,‡ modified	PSG	104	Sleep lab & Hospital			High risk vs. low risk	>5	86 (nd)	95 (nd)		C
Drager, 2010[101] 20381666	Berlin Questionnaire	PSG	99	Hospital			High risk vs. low risk	≥ 5	93 (82,98)	59 (43,73)		A
	ESS						10	≥ 5	49 (36,63)	80 (64,90)		

Balk EM, et al.. Diagnosis and Treatment of Obstructive Sleep Apnea in Adults. Comparative Effectiveness Review No. 32. AHRQ Publication No. 11-EHC052-EF. Rockville, MD: Agency for Healthcare Research and Quality, 2011.

Study PMID	Index test	Reference test	N	Setting	Subgroup	ROC Analysis					Quality
						Threshold, events/hr Index	PSG	Sensitivity, % (95% CI)	Specificity, % (95% CI)	AUC	
Crocker, 1990[102] 2368960	Statistical model *	PSG	105	Sleep lab		Probability of OSA >0.15	>15	92 (nd)	51 (nd)		B
Gurubhagavatula, 2001[103] 11734444	Clinical prediction rule, † derived	PSG	359	Sleep lab		Upper bound= 0.58 Lower bound= 0.14 ODI threshold= 5.02	≥5	94.1 (nd)	66.7 (nd)		A
						Upper bound = 0.9 Lower bound = 0.38 ODI threshold = 21	≥30	83.3 (nd)	94.7 (nd)		
Kushida, 1997[104] 9341055	Morphometric model ‡	PSG	300	Sleep lab		≥70	≥5	97.6 (95, 98.9)	100 (92,100)	0.996	C
Onen, 2008[105] 18775037	Observation-based Nocturnal Sleep Inventory (ONSI) §	PSG	115	Hospital		≥2 snoring episodes or ≥1 apnea episode	AHI≥15	89.7 (82, 97)	81.4 (70,93)		B
						≥5 snoring or ≥1 apnea	AHI≥15	56 (44, 68)	100		
						≥3 snoring or ≥1 apnea	AHI≥15	74 (63, 84)	93 (85,100)		
Rodsutti, 2004[106] 15283004	Clinical prediction rule, ** derived	PSG	243	Sleep lab		< 2.5	≥5	0 (nd)	89 (nd)		A
						2.5 - < 4.2	≥5	44 (nd)	85 (nd)	0.789	
						≥4.2	≥5	76 (nd)	60 (nd)		
Rowley, 2000[107] 11083602	Model #1 ††	PSG	370	Sleep lab	All	0.15	≥10	84 (nd)	39 (nd)	0.669	A
						0.95	≥20	33 (nd)	90 (nd)	0.7	
					Men	0.15	≥10			0.761	
					Women	0.15	≥10			0.633	
	Model #2 ‡‡				All	0.20	≥10	96 (nd)	13 (nd)	0.695	
						0.95	≥20	34 (nd)	87 (nd)	0.722	
					Men	0.2	≥10			0.801	
					Women	0.2	≥10			0.626	
	Model #3 §§				All	10	≥10	76 (nd)	54 (nd)	0.696	
						35	≥20	34 (nd)	89 (nd)	0.733	
					Men	10	≥10			0.707	
					Women	10	≥10			0.648	
	Model #4 ***				All	0.5	≥10	87 (nd)	35 (nd)	0.736	
						0.85	≥20	39 (nd)	93 (nd)	0.757	
					Men	0.5	≥10			0.801	
					Women	0.5	≥10			0.611	
Zerah-Lancner, 2000[108] 11112139	Based on Pulmonary function data †††	PSG	101	Sleep Lab		0.5	≥15	100 (nd)	84 (nd)		B

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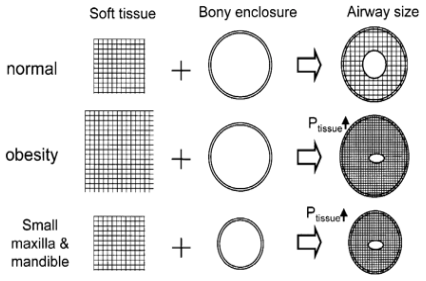
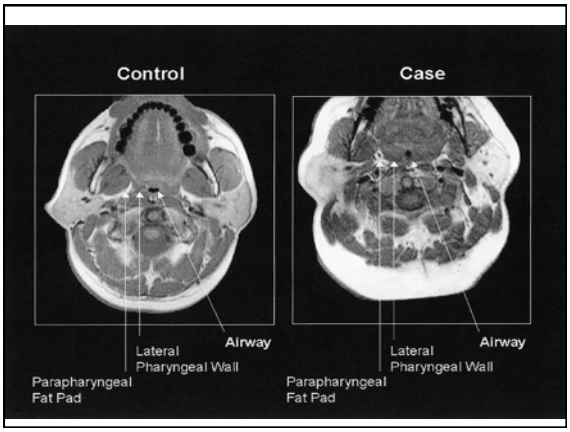
"...and on the box sat a fat and red-faced boy, in the state of somnolency." C. Dickens

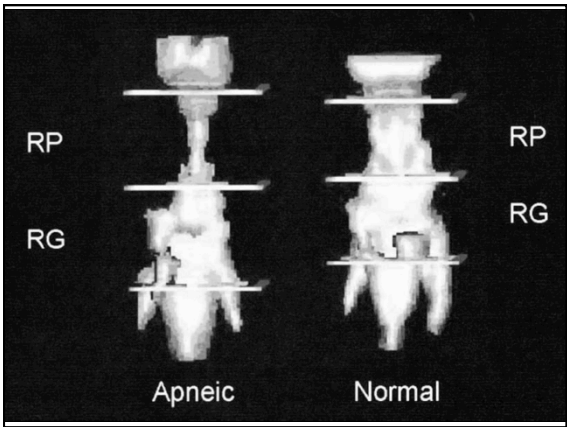
OSA Predisposing Factors

- Age (40 - 60 years)
- Male Gender (8 : 1 male : female)
- Hypothyroidism
- Medications, Alcohol
- Obesity
- Anatomic Abnormalities

Obesity, Craniofacial Dysmorphism and OSA







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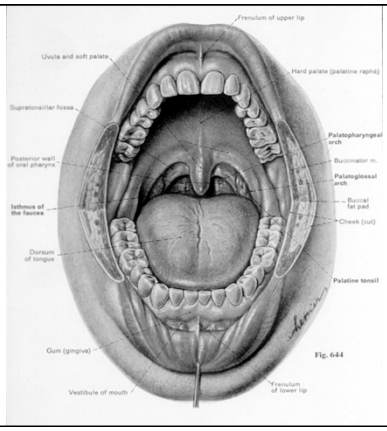
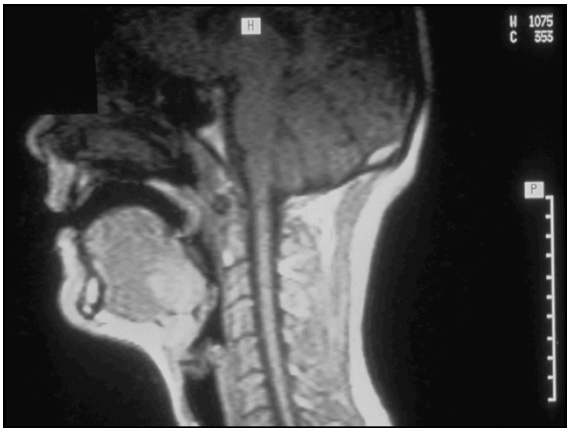
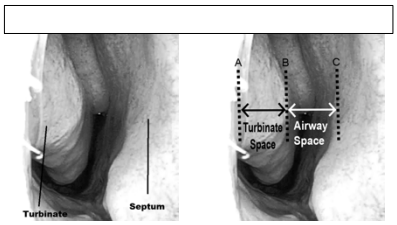






A = Lateral nasal wall
B = Medial aspect of the inferior turbinate
C = Nasal septum

Contributors to an Abnormal Upper Airway

- Excess, erythematous pharyngeal tissue
- Enlarged, erythematous uvula
- Macroglossia
- Congested nasal passages
- Low-lying soft palate
- High arched hard palate

Craniofacial Dysmorphism and OSA

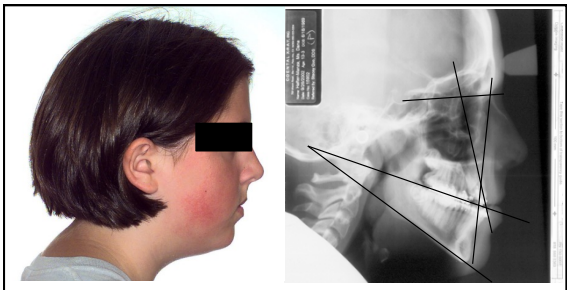
- Infants with apneas had family members with OSA, and small upper airways were a common familial feature
- Relatives of OSA patients reported more OSA symptoms and sleep-related breathing disorders, plus more evidence of craniofacial dysmorphism, compared to controls

Guilleminault, et al., 1986. Mathur and Douglas, 1995; Guilleminault, 1995

Craniofacial Dysmorphism Due to Non-Genetic Factors

- Early problems with nasal breathing such as nasal allergies have a negative impact on upper airway development.
- The increase in nasal resistance can halt growth of the maxillo-mandibular skeleton, and induced changes in the naso-maxillary, mandible, and pharyngeal airway space.
- Development of mouth breathing in association with an increase in nasal resistance, leads to mouth opening and mouth breathing during the day and night.
- This obligate mouth breathing and alteration in craniofacial growth are associated with OSA.

Harvold, E, Tomer, B, Vargervik, K, Chierici, G Primate Experiments on oral respiration. Am J Orthod 1981:79(4)359-372



- A tendency to have a retruded mandible (p=0.05)
- A greater inclination of the mandibular and occlusal planes (p<0.01)
- A tendency to have greater inclination of the upper incisors (p=0.08)

Juliano ML. Mouth breathing children have cephalometric patterns similar to those of adult patients with obstructive sleep apnea syndrome. Arq Neuropsiquiatr. 2009;67(3B):860-5.

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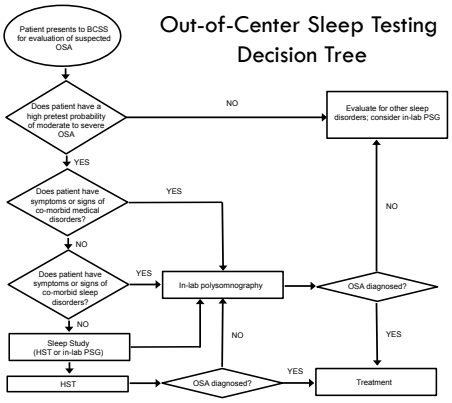
Management of OSA in patients during hospitalization and after discharge from the hospital?

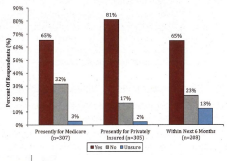
Out-of-Center Sleep Testing Decision Tree

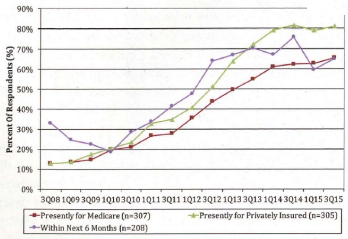


Collop NA et al. *J Clin Sleep Med* 2007;3(7):737-747

Out-of-Center Sleep Testing

Does your Sleep Center Administer Out-of-Center Sleep Tests?





Sleep Review. Third Quarter 2015 Sleep Center Survey Results (327 responses between 7/22/2015 and 8/10/2015), September 2015. sleepreviewmag.com

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  - What are OSA management options for patients prior to and following discharge from the hospital?

Treatment for Snoring* and OSA

PAP

Surgery*

Oral Appliances*

Nasal Valves and Stents*

Negative Pressure Devices

Weight Loss*

Behavior Modification*

Medications

Devices

- **CPAP** (continuous positive airway pressure): delivers single, fixed pressure
- **BPAP** (bilevel positive airway pressure): delivers inspiratory and expiratory pressures with or without backup rate
- **APAP** (auto-titrating positive airway pressure): delivers pressure based on flow signal at almost a breath-to-breath basis
- **ASV** (adaptive pressure support servo-ventilation): delivers a small but varying amount of ventilatory support

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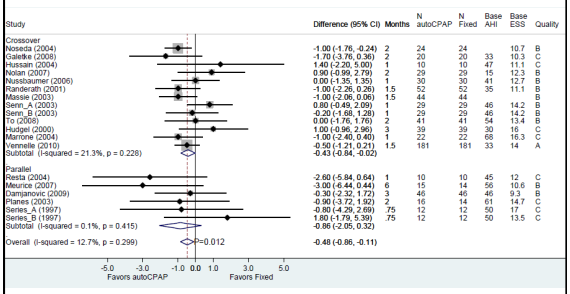
Fixed CPAP vs. APAP



Statistically but not clinically significant difference of 11 minutes of added use per night with APAP

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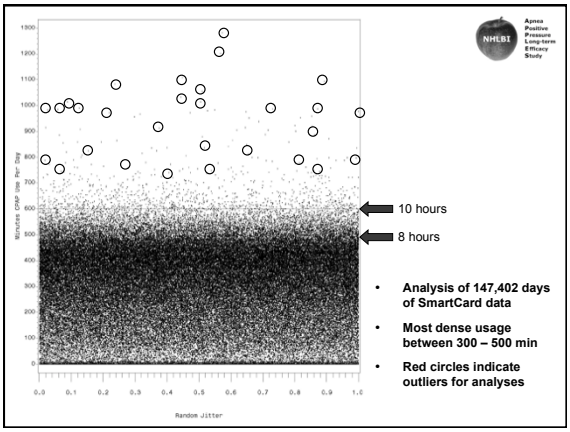
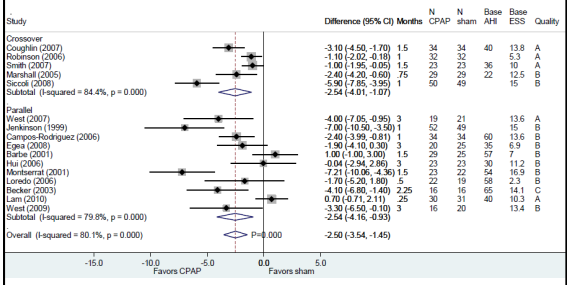


- **Analysis of 147,402 days of SmartCard data**
- **Most dense usage between 300 – 500 min**
- **Red circles indicate outliers for analyses**

CPAP Therapy and Daytime Sleepiness



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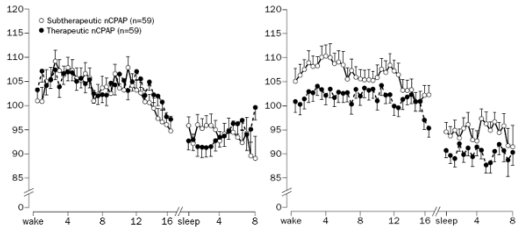
CPAP Therapy and HTN

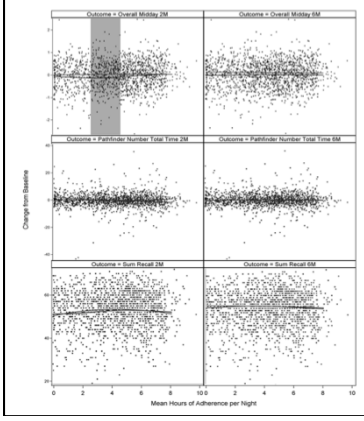


Pepperell JC, et al. Ambulatory blood pressure after therapeutic and subtherapeutic nasal continuous positive airway pressure for obstructive sleep apnoea: a randomised parallel trial. Lancet 2002; 359:204–210.

NCF in OSA Patients

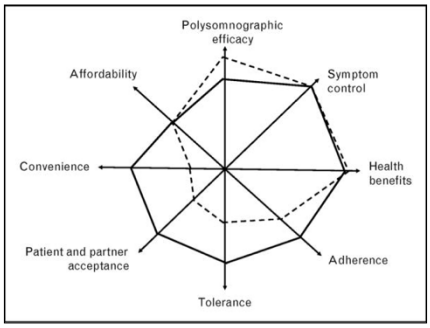
Author (Year)	Study Type	*n*	OSA Severity	Conclusions
Barbé (2001)	RCT	29/25	severe	no difference in Active vs. Sham CPAP groups for 8 A/P, L/M, and E/F tests
Bédard (1991)	CC	20/10	mod-severe	decrease* in 7/9 A/P and 2/4 E/F tests; decrease* in 5/6 L/M tests (only severe cases)
Cheshire (1992)	CS	29	mod-severe	correlation* between AHI and 1/2 EF tests and IQ decrease; no correlation in 3 A/P or 1 L/M tests
Findley (1986)	CS	26	severe	decrease* in 4/8 A/P, L/M, and E/F tests for hypoxemic vs. non-hypoxemic OSA subjects
Greenberg (1987)	CC	14/14	severe	decrease* in 7/14 A/P and E/F tests vs. controls
Ingram (1994)	CC	16/43	mild-severe	no difference in OSA vs. controls subjects ≥ 54 yrs for 1 A/P test
Kim (1997)	CH	199/642	mild-severe	negative association* between log AHI and psychomotor efficiency in 8 A/P, L/M, or E/F tests
Naëgelé (1995)	CC	17/17	severe	decrease* in 1/4 A/P tests, 8/10 L/M tests, and 3/9 E/F tests vs. controls
Presty (1991)	CS	119	mild-severe	decrease* in A/P and L/M tests for those OSA patients with severe hypoxia
Redline (1997)	CC	32/20	mild-mod	decrease* in 1/4 A/P tests and 1/5 E/F tests; no difference in 3 L/M tests vs. controls
Telakivi (1993)	CS	31	mild-severe	no correlation between hypoxia or sleepiness and 7 A/P, L/M, and E/F tests
Verstraeten (1996)	CC	26/22	mild-severe	no differences in OSAS vs. insomnia subjects for 6 A/P, L/M, or E/F tests

Significance Level:** $p < 0.05$; ***Study Type: RCT = randomized control trial; CC = case-control, CH = cohort; CS = case series; ***n:*** cases/controls (if applicable); ***OSA Severity*** by average Apnea-Hypopnea Index (AHI), with mild = 5 - 15 events/hr, moderate = 15 - 30 events/hr, and severe > 30 events/hr; ***Test Type:*** A/P = tests of attention and psychomotor function, L/M = tests of learning and memory, E/F = tests of executive and frontal-lobe function



CPAP Adherence-Adjusted Primary Neurocognitive Outcomes

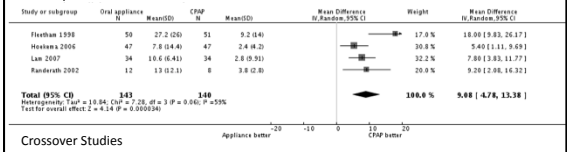
OA vs. PAP



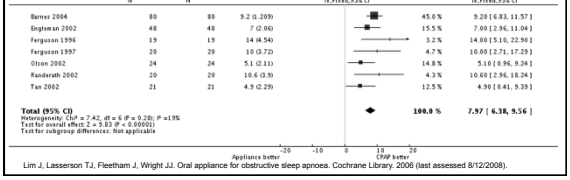
Chan AS, Cistulli PA. Oral appliance treatment of obstructive sleep apnea: an update. Curr Opin Pulm Med. 2009 Nov;15(6):591-6.

OA vs. PAP

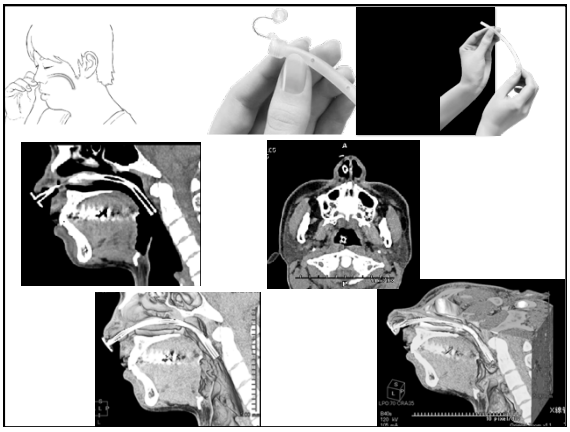
Parallel/First Arm Crossover Studies



Crossover Studies



Lim J, Lasserson TJ, Fleetham J, Wright JJ. Oral appliance for obstructive sleep apnoea. Cochrane Library. 2006 (last assessed 8/12/2008).



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Healthcare Transformation

- The practice of medicine is transforming to become more:
  - Efficient
  - Adaptable
  - Cost-Effective
  - Multidisciplinary
  - Patient-Centered

EVOLVE SLEEP
BY AASM

Hot Topics in Sleep Medicine http://evolvesleep.aasmnet.org/

SMART DOCS: a new patient-centered outcomes and coordinated-care management approach for the future practice of sleep medicine

SMART DOCS: a new patient-centered outcomes and coordinated-care management approach for the future practice of sleep medicine
The practice of medicine is currently undergoing a transformation to become more efficient, cost-effective, and patient centered in its delivery of care.

Kushida CA, Nichols DA, Holmes TH, et al. Sleep. 2015 Feb 1;38(2):315-26.

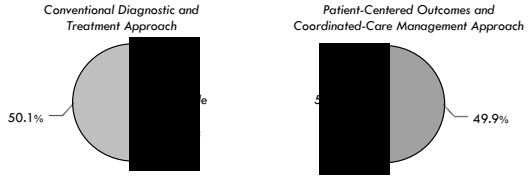
SMART DOCS Goals

- To introduce a new Patient-Centered Outcomes and Coordinated-Care Management (PCCM) approach for the future practice of sleep medicine
- To compare the PCCM approach to conventional (CONV) sleep medicine practice in a clinical trial evaluating:
  - Patient ratings of health care performance
  - Disease-specific outcomes
  - Global health measures
  - Health care utilization

Overall Study Sample

Randomized Clinical Trial
Includes new adult patients with signs/symptoms of a sleep disorder

1,836 Participants
56.6% Male
Average Age: 50.1 years



Management of Obstructive Sleep Apnea
Clete A. Kushida, M.D., Ph.D.
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PCCM Approach

- Using newer sleep medicine tools and technologies
  - More effective sleep disorder management

  Examples:
  - Continuous blood pressure monitoring
  - Wearable technology to track sleep-wake patterns

- Utilizing sleep medicine professionals in a primary care setting
  - Expedite diagnosis and treatment at front lines of care

  Example:
  - Establish a sleep disorder practice within primary care

PCCM Approach

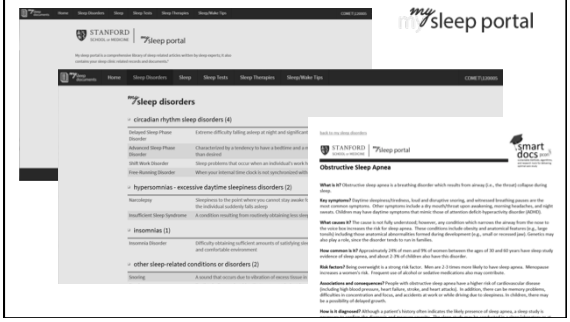
- Facilitating collaboration among sleep specialists, providers, patients, medical professional organizations, and industry
  - Stakeholder engagement for improved patient care

  Example:
  - Input on content/design for personalized patient materials
- Providing patients with better access to information, resources, and data about sleep disorders, comorbidities, treatments, and personal health information
  - More informed health care decisions

  Example:
  - Patient portal – my sleep portal

PCCM Sleep Education

- Patient Portal – Sleep Disorders



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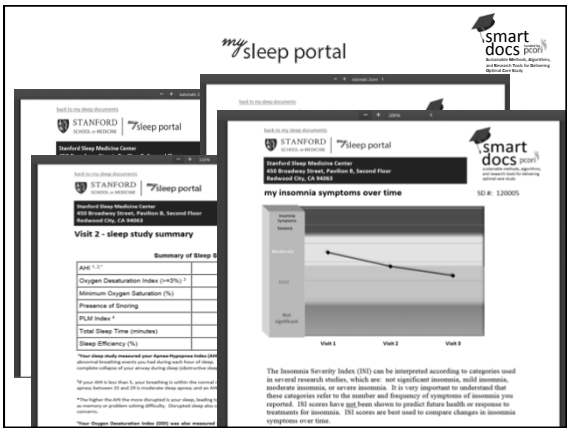


Obstructive Sleep Apnea

- includes branching logic and clinician report
- We use mainly out-of-center sleep testing (OCST) devices with ambulatory blood pressure monitoring for those who have borderline or definitive hypertension
- For those with high predictive probability for diabetes, measure glucose, insulin, and lipid levels
- Genetic markers (e.g., ApoE4) will be tested
- Adherence measures are uploaded to the web portal

Blood Pressure Monitoring

Obstructive Sleep Apnea

- Patients prescribed oral appliances have their probability of success and their target protrusive position assessed by the MATRx device
- There are integrated adherence monitoring devices in the OAs
- OA efficacy is evaluated with the OCST devices or in-lab polysomnograms
- OA efficacy and adherence data are placed on the web portal

Oral Appliance Titration

Adherence Measures

Tools and Technologies

- Alliance Sleep Questionnaire
- Greater use of OCSTs
- Ambulatory blood pressure assessments (SOMNOtouch)
- Oral appliance titration (MATRx)
- Oral appliance adherence assessment (TheraMon)
- Sleep-wake patterns, fitness, nutrition (Jawbone UP24)
- Cognitive behavioral therapy for insomnia (SleepRate)
- Salivary dim light melatonin onset (DLMO)
- Diabetic risk assessment, inflammatory markers
- Genetic markers

Primary Care

Sleep physician, nurses, and technologists at PCP office to:

- Assist in patient evaluation and referral decisions
- Order and set-up home sleep studies at PCP office
- Promptly attend to management issues, e.g., sub-optimal adherence, CBTI instruction

Coordinated Care

- Sleep technologists with Certification in Clinical Sleep Health™ (CCSH) "work directly with sleep medicine patients, families, and practitioners to coordinate and manage patient care, improve outcomes, educate patients and the community, and advocate for the importance of good sleep."
- Contact patients within one week after sleep studies and after receiving PAP to address any questions or issues.

Outcomes

Impact on Improved Health Care Performance

Primary Endpoint: Consumer Assessment of Healthcare Providers and Systems Clinician and Group Survey (CGCAHPS) Global Provider Rating

Secondary Endpoint: Items on "How Well Providers (or Doctors) Communicate with Patients"

Secondary Endpoint: Items on the CGCAHPS Health Information Technology Item Set

Impact on Cost Containment

Secondary Endpoint: Out-of-pocket costs

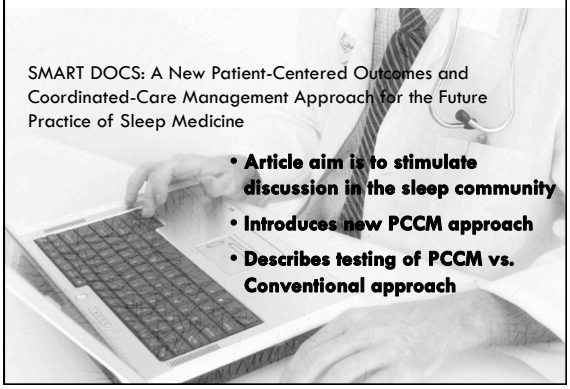
Outcomes

Impact on Improved Health

Primary Endpoint: SF-36 Vitality Component Score
Secondary Endpoint: SF-6D Health Utility index
Secondary Endpoint: FOSQ-10
Secondary Endpoint: SF-36 Physical Component Score
Secondary Endpoint: Alliance Sleep Questionnaire (ASQ)
Disorder Specific Measures
Epworth Sleepiness Scale (ESS, normative value 12.0 ± 4.0)
Insomnia Severity Index (ISI, normative value 20.0 ± 5.0)
International Restless Legs Syndrome Study Group Rating

SMART DOCS

STANFORD SCHOOL OF MEDICINE



SMART DOCS: A New Patient-Centered Outcomes and Coordinated-Care Management Approach for the Future Practice of Sleep Medicine

- **Article aim is to stimulate discussion in the sleep community**
- **Introduces new PCCM approach**
- **Describes testing of PCCM vs. Conventional approach**