WatchPAT™

Clinical Compendium
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WatchPAT™ Clinical Compendium Mar 2017

OSA validation against Polysomnography (PSG)

Sleep Stages and Sleep/Wake Validation Against PSG

AFib

Therapeutics

Transportation

ENT & Dental

General Home Sleep Testing

OSA validation against PSG

1

Diagnosis of Obstructive Sleep Apnea by Peripheral Arterial Tonometry (Meta - analysis)
Yalamanchali et al. JAMA Otolaryngol Head Neck Surg, 2013.5338
http://www.ncbi.nlm.nih.gov/pubmed/24158564

Objective:

- To assess the correlation between sleep indexes measured by a portable sleep testing device [Peripheral Arterial Tonometry (PAT®)] and those measured by PSG.

Methods:

- The authors searched PubMed, MEDLINE, the Cochrane Trial Registry (through May 2013), and relevent article bibliographies.
- Review incl. studies that assessed correlatioon of sleep indexes between PAT devices and PSG in adults (age>18 years).
- 14 studies qualified the inclusion criteria (909 patients) in which analysis provided a bi-variate correlation coefficient for sleep indexes, specifically the respiratory disturbance index (RDI), apnea hypopnea (AHI), and oxygen desaturation index (ODI).
- The studies were reviewed by 2 independent reviewers. Reported correlation values for the RDI, AHI and ODI between a commercially available PAT device (WatchPAT) and PSG were systematically reviewed.

Results:

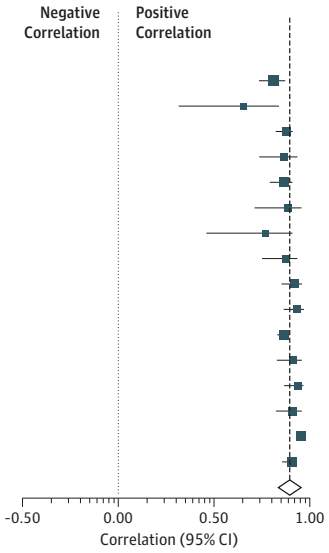
- Overall, correlation of the RDI and AHII was high (r=0.889 [95%CI, 0.862-0.911];P<0.001). Studies companring the RDI between PAT and PSG had a combined correlation of 0.879 (98%CI, 0.849-0.904;P<0.001); those comparing the AHI, 0.893 (0.857-0.920;P<0.001); and those comparing the ODI, 0.942 (0.894-0.969;P<0.001).

Key Takeaways:

- Compared with PSG, the PAT ambulatory test offered the possibility of an accurate dignosis with convenience and low cost. PAT consistently demonstrated a high degree of correlation in sleep variables when compared to PSG.

Overall Correlation of the Respiratory Disturbance Index (RDI) and Apnea-Hypopnea Index (AHI) Between Polysomonography (PSG) and Peripheral Arterial Tonometry (PAT)

Source (Study Setting), (Design)	Subgroup Within Study	Correlation, *r* Value	Statistics: Lower Limit (95% CI)	Statistics: Upper Limit (95% CI)	*Z* Value	*P* Value
Pillar et al,[17] 2002 (L), (B)	AHI[a]	0.820	(0.740-0.877)		11.035	<.001
Penzel et al,[18] 2002 (L), (B)	AHI	0.656	(0.313-0.848)		3.334	.001
Bar et al,[19] 2003 (L), (B)	AHI[a]	0.880	(0.826-0.918)		13.480	<.001
Ayas et al,[20] 2003 (L), (B)	AHI	0.870	(0.742-0.937)		6.927	<.001
Pillar et al,[21] 2003 (L), (B)	AHI[a]	0.870	(0.797-0.918)		10.748	<.001
Penzel et al,[22] 2004 (L), (B)	AHI	0.890	(0.715-0.960)		5.320	<.001
Penzel et al,[22] 2004 (L), (B)	RDI	0.770	(0.459-0.913)		3.818	<.001
Pittman et al,[23] 2004 (L), (B)	AHI[a]	0.880	(0.758-0.943)		7.015	<.001
Pang et al,[25] 2007 (L), (B)	AHI	0.929	(0.858-0.965)		8.883	<.001
Choi et al,[26] 2010 (L), (NB)	AHI	0.940	(0.867-0.974)		8.152	<.001
Hedner et al,[27] 2011 (L), (B)	RDI	0.870	(0.834-0.898)		19.962	<.001
Onder et al,[30] 2012 (L), (B group 1)	AHI	0.920	(0.835-0.962)		8.102	<.001
Onder et al,[30] 2012 (L), (B group 2)	AHI	0.940	(0.871-0.973)		8.515	<.001
Weimin et al,[32] 2013 (L), (B)	AHI	0.920	(0.833-0.963)		7.945	<.001
Yuceege et al,[31] 2013 (L), (B)	AHI	0.960	(0.939-0.974)		17.621	<.001
Yuceege et al,[31] 2013 (L), (B)	RDI	0.909	(0.863-0.940)		13.780	<.001
Overall		0.894	(0.864-0.918)		21.241	<.001



corresponds to the relative weight assigned in the pooled analysis. B indicates blinded; H, home setting; L, laboratory setting; and NB, non-blinded. Study reported the value as RDI; however, recent American Academy of Sleep Medicine criteria defined the value as AHI.

adherence

OSA validation against PSG

2

Validating a Portable Monitoring Device for Sleep Apnea Diagnosis in a Population Based Cohort Using Synchronized Home Plysomnography.
Zou D, Grote L, Peker Y, Lindblad U, Hedner
http://www.ncbi.nlm.nih.gov/pubmed/16553023

Objective:

- To assess the accuracy of the WatchPAT device based on Peripheral Arterial Tonometry (PAT) to diagnose Obstructive Sleep Apnea (OSA).
- To propose a new standard for HST validation using synchronized polysomnography (PSG) home recordings and a population based cohort.

Methods:

- A single comparative unattended PSG and WatchPAT sleep test, at home environment recorded in a synchronized manner.
- Subject consecutively recruited from the Skaraborg Hypertension and Diabetes Project.
- Data included ninety-eight subjects (55 men; age, 60 ± 7 year; body mass index, 28 ± 4 kg/m2)

Results:

- Mean PSG-AHI was 25.5 +/- 22.9 events per hour.
- WatchPAT RDI, AHI, and ODI correlated closely with corresponding PSG indices (R=0.88, 0.90, and 0.92; p < .0001, respectively) .
- The areas under the curve for the ROC curves for WatchPAT AHI and RDI were 0.93 and 0.90 for PSG-AHI and RDI thresholds 10 and 20 (p < .0001, respectively).
- Agreement of the sleep-wake assessment based on 30-second bins between the 2 systems was 82 +/- 7%

Conclusion:

- WatchPAT was reasonably accurate for unattended home diagnosis of OSA in a population sample not preselected for OSA symptoms.
- Simultaneous home PSG is proposed as a validation standard for assessment of simplified recording tools for OSA diagnosis.

Key Takeaways:

- The WatchPAT HST offers an accurate and simple diagnosis of OSA with minimal number of sensors for the patient to apply.
- The WatchPAT is the only HST that has been validated in the unattended home settings by simultaneous recording with PSG.

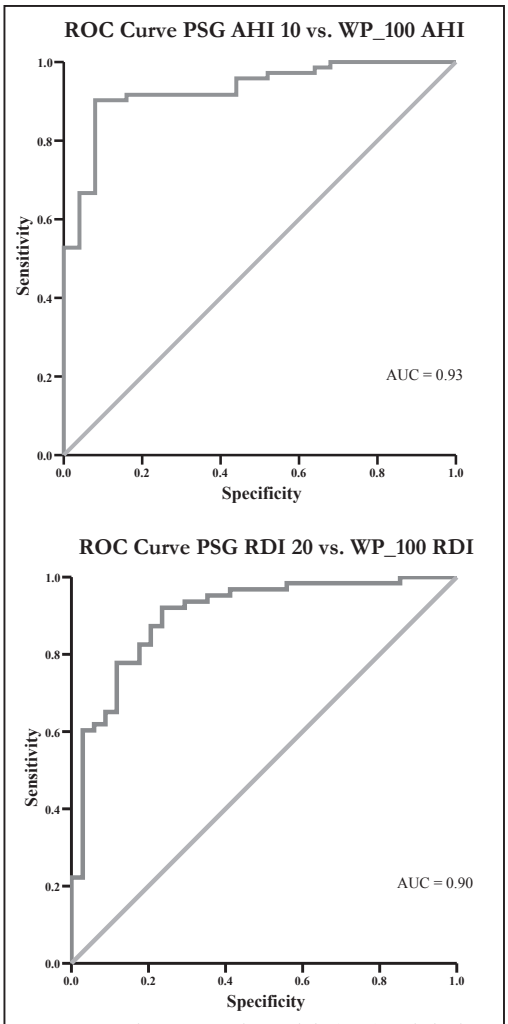


Figure 4—Receiver-operator characteristic (ROC) analysis shows the specificity and sensitivity for obstructive sleep apnea diagnosis of Watch_PAT 100 (WP_100) in this population (cut-off polysomnography [PSG] apnea-hypopnea index [AHI] >10 [a] and PSG respiratory disturbance index [RDI] > 20 [b] area under the curves [AUC] of 0.93 and 0.90, p < .0001, respectively).

Table 2—Sleep and breathing characteristics comparing Polysomnography and Watch_PAT 100

Sleep Parameter	Monitoring Method	
	Polysomnography	WP_100
TST	6.5±1.2	6.3±1.3
AHI	25.5±22.9	27.0±18.7
RDI	31.6±22.7	30.4±18.7
ODI	13.3±15.3	17.7±16.7*

Data are presented as mean ± SD events per hour, except total sleep time (TST), which is given in hours. WP_100 refers to Watch_PAT 100; AHI, apnea-hypopnea index; RDI, respiratory disturbance index; ODI, oxygen desaturation index.
*p < .0001

alence of OSA in the adult population very high, but numbers also may be anticipated to increase even further as obesity increases dramatically in industrialized countries.[27] There is also a growing insight from clinicians in hypertension clinics, stroke units, and cardiology wards that a diagnosis of OSA may affect prognosis and therapeutic strategies. The combination of high prevalence and a complex method of investigation generate a considerable public burden of cost as well as long waiting lists in many sleep laboratories.

This dilemma has sparked the development of simpler and po-

OSA validation against PSG

3 Portable Monitoring and Autotitration versus Polysomnography for the Diagnosis and Treatment of Sleep Apnea
Berry et al., Sleep. 2008 Oct; 31(10):1423-31
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2572748/

Objective:

- To compare a clinical pathway using portable monitoring (PM) for diagnosis and unattended autotitration of positive airway pressure (APAP), for selecting an effective continuous positive airway pressure (CPAP), with a pathway using polysomnography (PSG) for diagnosis and treatment of obstructive sleep apnea (OSA).

Methods:

- 106 patients with daytime sleepiness and a high likelihood of having OSA were randomized to the PSG pathway or the WatchPAT–APAP pathway.

Results:

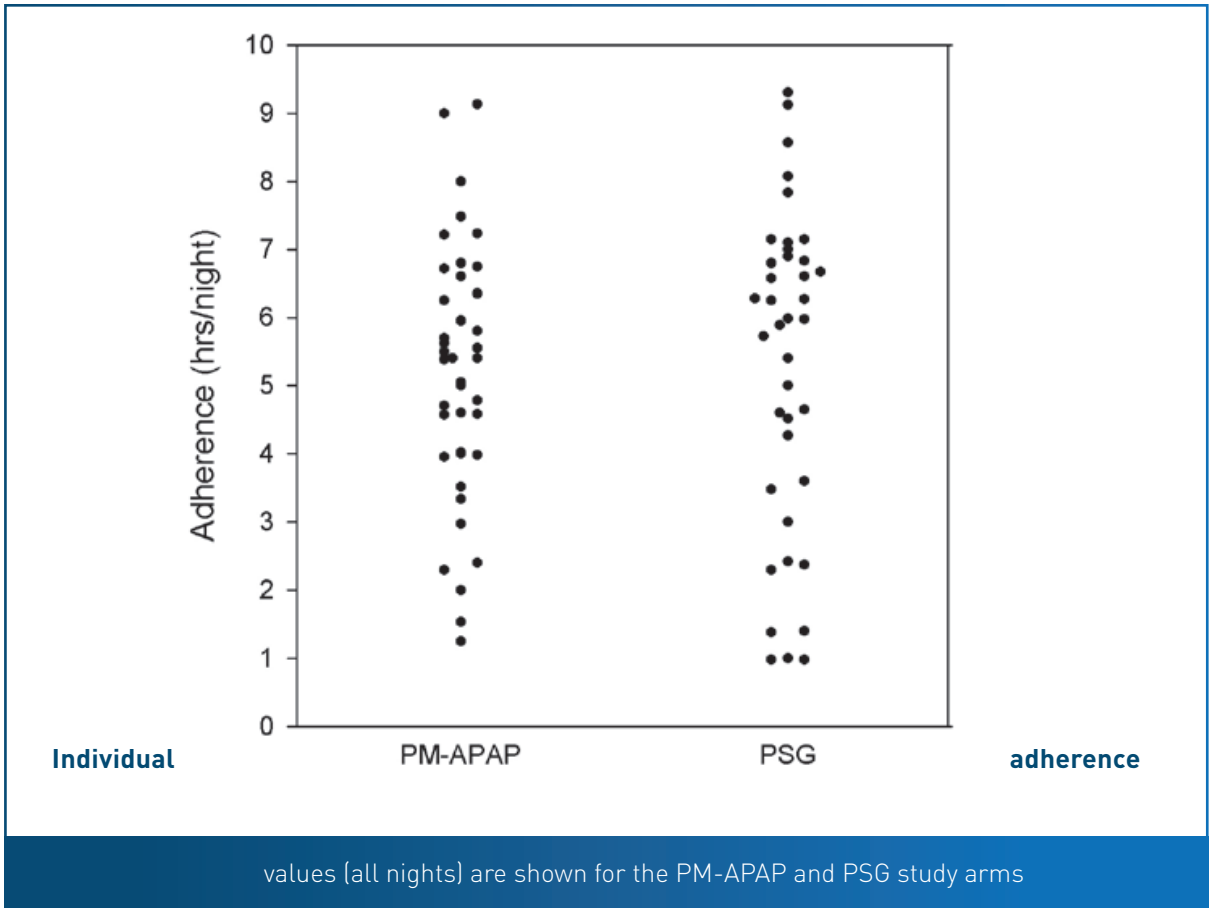
- The AHI in the PM-APAP group was 29.2 ± 2.3/h and in the PSG group was 36.8 ± 4.8/h (P= NS).
- Patients with an AHI >5 were offered CPAP treatment. Those accepting treatment (WatchPAT-APAP 45, PSG 43) were begun on CPAP using identical devices at similar mean pressures (11.2 ± 0.4 versus 10.9 ± 0.5 cm H2O).
- At a clinic visit 6 weeks after starting CPAP, 40 patients in the WatchPAT-APAP group (78.4% of those with OSA and 88.8% started on CPAP) and 39 in the PSG arm (81.2% of those with OSA and 90.6% of those started on CPAP) were using CPAP treatment (P = NS).
- The mean nightly adherence (WatchPAT-APAP: 5.20 ± 0.28 versus PSG: 5.25 ± 0.38 h/night), decrease in Epworth Sleepiness Scale score (−6.50 ± 0.71 versus −6.97 ± 0.73), improvement in the global Functional Outcome of Sleep Questionnaire score (3.10 ± 0.05 versus 3.31 ± 0.52), and CPAP satisfaction did not differ between the groups.

Conclusion:

- A clinical pathway utilizing WatchPAT and WatchPAT APAP titration resulted in CPAP adherence and clinical outcomes similar to one using PSG.

Key Takeaways:

- The WatchPAT can be used for the full cycle of diagnosing and treating OSA.
- This is a perfect option for remote areas, where sleep centres are few or in large medical facilities where waiting lists delay assessment and treatment of OSA.



values (all nights) are shown for the PM-APAP and PSG study arms

Table 4—Treatment Outcomes

	PM-APAP	PSG	P
Change in ESS	−6.50 ± 0.71	−6.97 ± 0.73	NS
Change in FOSQ	3.10 ± 0.05	3.31 ± 0.52	NS
CPAP satisfaction Questionnaire (3-15), 15 most satisfied	12.8 ± 0.4	12.2 ± 0.2	NS
Machine estimate of residual AHI (/hour)	3.5 ± 0.3	5.3 ± 0.7	NS

Sleep Stages and Sleep/Wake Validation Against PSG

4

Sleep Staging Based on Autonomic Signals: A Multi-Center Validation Study
Hedner et al., J Clin Sleep Med. 2011 Jun 15; 7(3): 301–306
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3113970/

Objective:

- To assess the WatchPAT based algorithm for determining wake, light sleep, deep sleep, and REM sleep based on epoch-by-epoch comparisons to PSG.

Methods:

- Total of 237 patients data was analyzed (38 normal; 189 with obstructive sleep apnea [OSA])
- Subjects underwent simultaneous, synchronized overnight recordings with PSG and the WatchPAT
- Light/deep sleep and REM sleep from the WatchPAT recording was automatically scored based on features extracted from time series of Peripheral Arterial Tone amplitudes and interpulse periods.
- The PSG-scored sleep stages 1 and 2 were classified as light sleep for epoch-by-epoch comparisons.

Results:

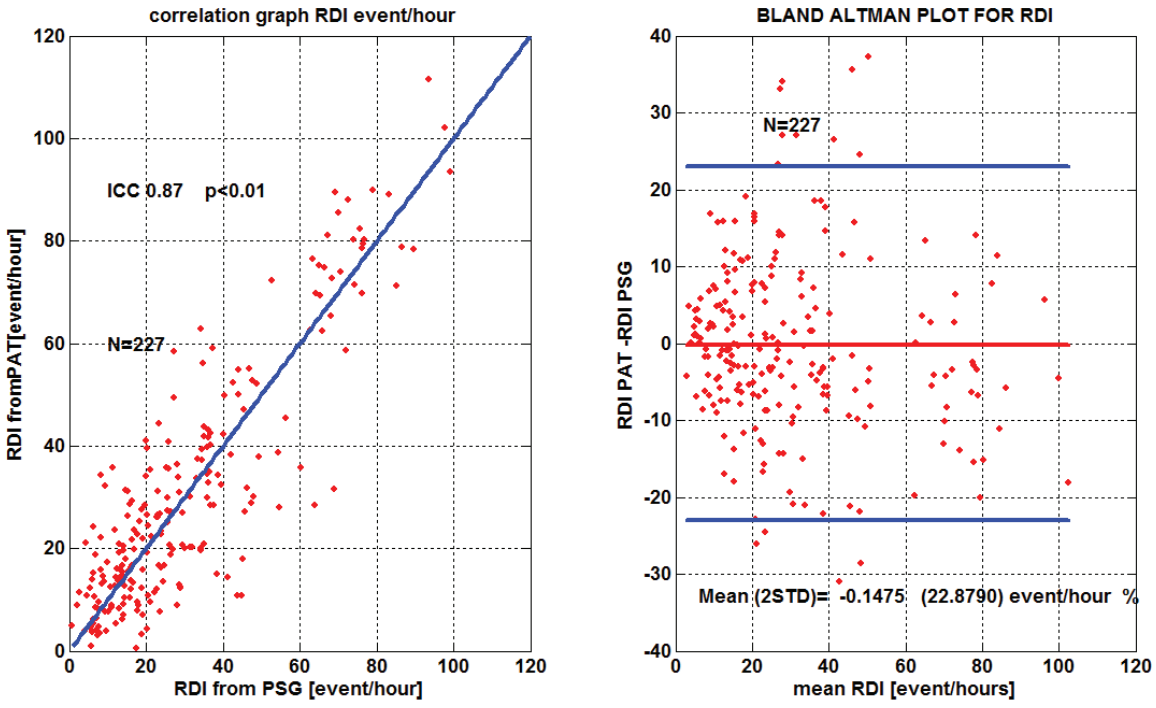
- The overall agreement in detecting light/deep and REM sleep were 88.6% ± 5.9% and 88.7% ± 5.5%, respectively.
- There was good agreement between PSG and the WatchPAT in quantifying sleep efficiency (78.4% ± 9.9% vs. 78.8% ± 13.4%), REM latency (237 ± 148 vs. 225 ± 159 epochs), and REM percentage (14.4% ± 6.5% vs. 19.3% ± 8.7%).
- OSA severity did not affect the sensitivity and specificity of the algorithm.

Conclusion:

- WatchPAT can detect sleep stages with moderate agreement to PSG in normal subjects and OSA patients. This novel algorithm may provide insights on sleep and sleep architecture when applying the PAT recorder for OSA diagnosis.
- This study shows that sleep staging based on actigraphy and signals recorded by the WatchPAT is of reasonable accuracy. This may be of substantial interest and importance in the era of a shift toward unattended home sleep testing.

Key Takeaways:

- Sleep architecture, obtained by the WatchPAT analysis, provides important added information to the physician when assessing the sleep test. This is mostly important when assessing results of mild OSA where patients with mild OSA presenting poor sleep architecture may be treated while a patient with mild OSA but normal sleep architecture may not be treated.
- Sleep architecture enables diagnosis of REM related OSA and insomnia.



Interclass correlation and Bland Altman plot for the scoring of respiratory disturbance index (RDI) The interclass correlation between the methods was r = 0.87, p < 0.01. On the right, the X axis represents the mean RDI between the PSG and the PAT recorder, and the Y axis the difference between methods.

Sleep Stages and Sleep/Wake Validation Against PSG

5 Detecting REM Sleep From the Finger: Automatic REM Sleep Algorithm Based on Peripheral Arterial Tone (PAT) and Actigraphy
Herscovici et al., Physiol Meas 2007; 28(2): 129-140
http://sleepmedicinenetwork.org/pdf/WatchPat/Lavie-DetectingREMsleepfromthefinger.pdf

Objective:

- To evaluate an automatic REM detection algorithm based on the Peripheral Arterial Tone (PAT) and actigraphy signals recorded with the WatchPAT.

Methods:

- The algorithm was developed using a training data set of 30 patients recorded simultaneously with polysomnography (PSG) and WatchPAT in a synchronized manner.
- Sleep records were divided into 5 min intervals and two time series were constructed from the PAT amplitudes and PAT-derived interpulse periods in each interval.
- A prediction function based on 16 features extracted from the above time series that determines the likelihood of detecting a REM epoch was developed.
- The coefficients of the prediction function were determined using a genetic algorithm (GA) optimization process, tuned to maximize a price function depending on the sensitivity, specificity and agreement of the algorithm in comparison with the PSG manual scoring.

Results:

- Based the validation set of 30 patients, overall sensitivity, specificity and agreement of the automatic algorithm to identify standard 30 sepochs of REM sleep were 78%, 92%, 89%, respectively.

Conclusion:

- Deploying this REM detection algorithm in the WatchPAT device could be very useful for unattended ambulatory sleep monitoring.
- The innovative method of optimization using a genetic algorithm has been proven to yield robust results in the validation set.

Key Takeaways:

- The convenience of obtaining information on REM sleep with the WatchPAT may be valuable in assessing the effect of OSA on sleep structure and identifying patients with REM-related sleep apnea.
- As post-treatment increase in REM sleep is associated with subjective improvement in

sleep quality, this added feature of the Watch PAT will be useful in evaluating the efficacy of treatment in sleep apnea patients.

- Sleep architecture enables diagnosis of REM related OSA and insomnia.

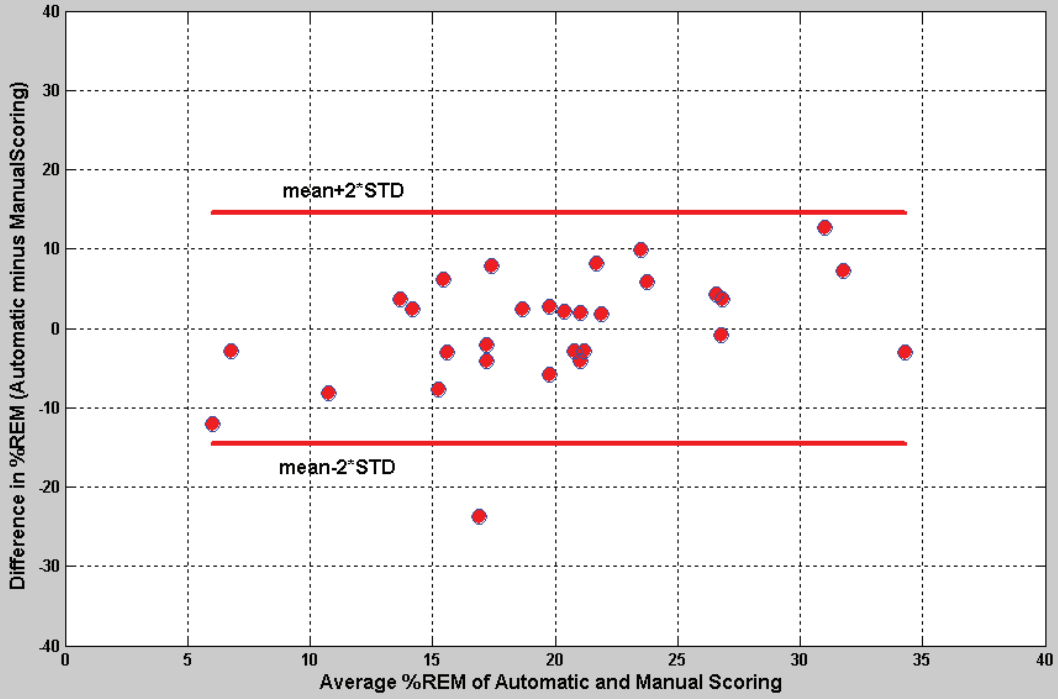


Figure 3. A graph describing the Bland-Altman of error in%REM detection versus mean value of % REM from the polysomnography (PSG) and the automatic REM detection algorithm (ARDA). Error in % REM = ARDA % REM – PSG % REM.

Sleep Stages and Sleep/Wake Validation Against PSG

6

Obstructive Sleep Apnea During REM Sleep and Hypertension
Mokhlesi et al., American Journal of Respiratory and Critical Care Medicine 2014; 190(10): 1158-1167
http://europepmc.org/abstract/med/25295854 *supporting non-WP paper

Objective:

- To quantify the independent association of OSA during REM sleep with prevalent and incident hypertension.

Methods:

- Study population: adults enrolled in the longitudinal community-based Wisconsin Sleep Cohort Study with at least 30 minutes of REM sleep obtained from overnight in-laboratory polysomnography (PSG).
- Studies were repeated at 4-year intervals to quantify OSA.
- Repeated measured logistic regression models were fitted to explore the association between REM sleep OSA and prevalent hypertension in the entire cohort (n = 4,385 sleep studies on 1,451 individuals) and additionally in a subset with ambulatory blood pressure data (n = 1,085 sleep studies on 742 individuals).
- Conditional logistic regression models were fitted to longitudinally explore the association between REM OSA and development of hypertension.
- All models controlled for OSA events during non-REM sleep, either by statistical adjustment or by stratification.

Results:

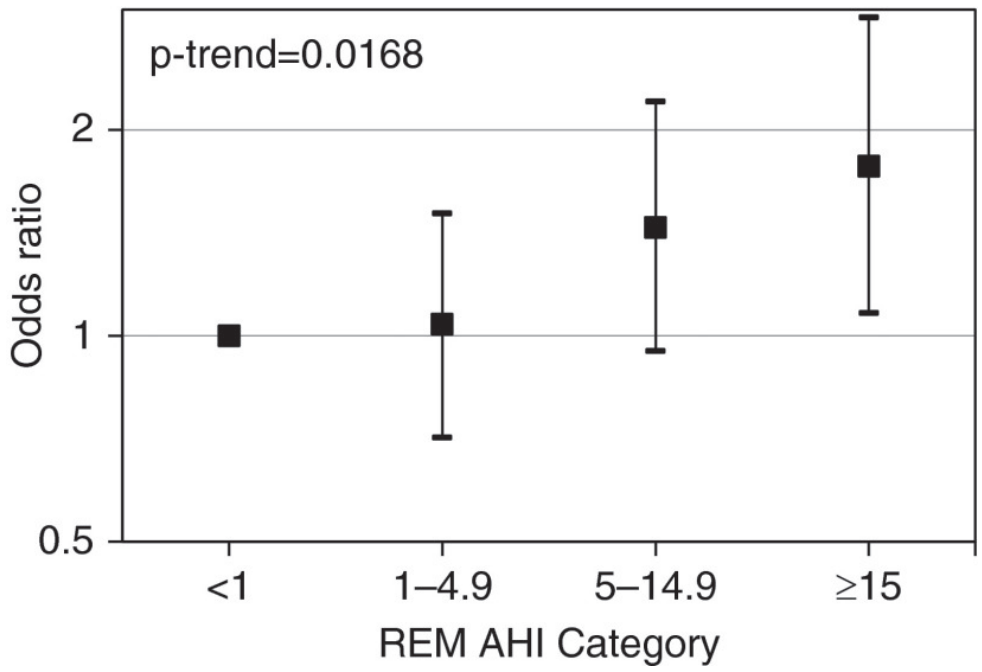
- Fully adjusted models demonstrated significant dose-relationships between REM Apnea-Hypopnea Index (AHI) and prevalent hypertension.
- Increased relative odds of hypertension were most evident with REM AHI greater than or equal to 15.
- In individuals with non-REM AHI less than or equal to 5, a two-fold increase in REM AHI was associated with 24% higher odds of hypertension (odds ratio, 1.24; 95% confidence interval, 1.08-1.41).
- Longitudinal analysis revealed a significant association between REM AHI categories and the development of hypertension (P trend = 0.017).
- Non-REM AHI was not a significant predictor of hypertension in any of the models.

Conclusion:

- REM OSA is cross-sectionally and longitudinally associated with hypertension.
- This is clinically relevant because treatment of OSA is often limited to the first half of the sleep period leaving most of REM sleep untreated.

Key Takeaways:

- REM-related OSA may identify patients minimally symptomatic and frequently do not complain of excessive daytime sleepiness, which may lead to delay in diagnosis and therapy.
- Without detection of REM related OSA, patient might not be treated, exposing the patient to higher risk of HP.
- As post-treatment increase in REM sleep is associated with subjective improvement in sleep quality, this added feature of the WatchPAT will be useful in evaluating the efficacy of treatment in sleep apnea patients.



Adjusted odds ratio for estimating the risk of developing hypertension based on REM apnea–hypopnea index (AHI) severity categories. Conditional logistic regression model fitted to longitudinally explore the independent association between obstructive sleep apnea during REM sleep and development of hypertension. Estimates are adjusted for age, body mass index, waist-to-hip ratio, smoking, alcohol, and log non-REM AHI. The P value for log2(non-REM AHI + 1) was 0.28.

Sleep Stages and Sleep/Wake Validation Against PSG

7 Differentiating Between Light and Deep Sleep Stages Using an Ambulatory Device Based on Peripheral Arterial Tonometry

Bresler et al., Physiol Meas. 2008; 29(5): 571-584
http://iopscience.iop.org/article/10.1088/0967-3334/29/5/004/meta;jsessionid=0FB0586C5282E1F11F6302BE6E47DB49.c1

Objective:

- Assessment of an automatic algorithm based on Peripheral Arterial Tone (PAT) measured by WatchPAT to differentiate between light, deep and REM sleep stages, in addition to NREM and REM sleep differentiation.

Methods:

- Patients underwent simultaneous recording of the WatchPAT device and PSG in a synchronized manner.
- The algorithm was developed using a training set of 49 patients.
- Algorithm was validated using a separate set of 44 patients.

Results:

- Overall sensitivity, specificity and agreement of the automatic algorithm to identify standard 30 s epochs of light and deep sleep stages were as follows:
  For the training set – sensitivity 66%, specificity 89%, agreement 82%; for the validation set – sensitivity 65%, specificity 87% and agreement 80%.

Conclusion:

- Together with the previous algorithms for REM, NREM and wake detection, the capability provides a close to full stage detection method based solely on PAT and actigraphy signals, which could be very useful for unattended ambulatory sleep studies when EEG recordings are not available.

Key Takeaways:

- The WatchPAT can be a feasible alternative to costly in-lab sleep tests as it can provide information about the patient's sleep architecture, providing additional information for assessing OSA severity (especially in mild or moderate OSA), in addition to detection of REM related OSA.

Table 2. Sensitivity, specificity and agreement mean values by subject for the three groups.

	Group 1, RDI $<$ 20	Group 2, 20 $<$ RDI $<$ 40	Group 3, RDI $>$ 40
Sensitivity (%)	61 $\pm$ 26	55 $\pm$ 23	72 $\pm$ 32
Specificity (%)	89 $\pm$ 10	87 $\pm$ 13	87 $\pm$ 6
Agreement (%)	82 $\pm$ 7	78 $\pm$ 13	85 $\pm$ 6

Sleep Stages and Sleep/Wake Validation Against PSG

8 A Novel Adaptive Wrist Actigraphy Algorithm for Sleep-Wake Assessment in Sleep Apnea Patients

Hedner et al., SLEEP 2004; 27(8):1560-6516
http://journalsleep.org/ViewAbstract.aspx?pid=26087

Objective:

- To validate a novel automatic algorithm, developed for actigraphic studies in normal subjects and patients with obstructive sleep apnea, by comparing it on an epoch-by-epoch basis to PSG.

Methods:

- A total of 228 subjects from 3 different sleep centers participated.
- Simultaneous synchronized recording of PSG and WatchPAT an ambulatory device with a built-in actigraph.
- The automatic sleep/wake algorithm is based on both the quantification of motion (magnitude and duration) and the various periodic movement patterns, such as those occurring in patients with moderate to severe Obstructive Sleep Apnea.

Results:

- The overall sensitivity and specificity to identify sleep was 89% and 69%, respectively. The agreement ranged from 86% in normal subjects to 86%, 84%, and 80% in the patients with mild, moderate, and severe OSA, respectively.
- There was a tight agreement between actigraphy and PSG in determining sleep efficiency (78.4 +/- 9.9 vs 78.8 +/- 13.4%), total sleep time (690 +/- 152 vs 690 +/- 154 epochs), and sleep latency (56.8 +/- 31.4 vs 43.3 +/- 45.4 epochs).
- For most individuals differences between PSG and actigraphy were relatively small, but for some there was a substantial disagreement.

Conclusion:

- The new actigraphy algorithm provides a reasonably accurate estimation of sleep and wakefulness in normal subjects and OSA patients.
- This simple method for assessment of total sleep time may provide a useful tool to facilitate accurate quantification of Obstructive Sleep Apnea in the home environment.

Key Takeaways:

- The WatchPAT HST offers an accurate diagnosis of OSA as sleep indices are based on total sleep time (TST) and not on total recording time (TRT). This affects mostly patients with mild to moderate OSA
- The WatchPAT is the only HST that provides TST for the calculation of sleep disturbance indices.

Table 4—Sleep Indexes in the Groups with the Various Severities of Obstructive Sleep Apnea

Level of OSA severity	Sleep Efficiency, %		Total Sleep Time, epochs		Sleep Latency, epochs	
	PSG	ASWA	PSG	ASWA	PSG	ASWA
Normal	79.2 ± 14.9	79.6 ± 11.6	666 ± 175	670 ± 177	51.2 ± 52.6	62.2 ± 33.2
Mild	80.7 ± 12.2	80.6 ± 8.4	707 ± 134	707 ± 121	37.8 ± 38.8	54.4 ± 27.1*
Moderate	80.0 ± 12.1	79.4 ± 9.2	702 ± 152	702 ± 158	39.9 ± 36.7	54.4 ± 30.8*
Severe	74.7 ± 14.9	73.6 ± 9.8	673 ± 162	667 ± 152	48.6 ± 57.0	59.1 ± 35.2
All	78.8 ± 13.4	78.4 ± 9.9	690 ± 154	690 ± 152	43.3 ± 45.4	56.8 ± 31.4*

*$P < .05$ polysomnography (PSG) vs automatic sleep-wake analysis (ASWA). OSA refers to obstructive sleep apnea.

Sleep Stages and Sleep/Wake Validation Against PSG

9

Comparison of AHI Using Recording Time versus Sleep Time
Schutte – Rodin et al., J Sleep Abs supl 2014, p. A373 *supporting non-WP paper
http://www.journalsleep.org/Resources/Documents/2014AbstractSupplement.pdf (page A373-A374)

Objective:

- To compare the HST-AHI and PSG-AHI using existing PSG data.
- To determine if different AHI calculation methods change the patient's categorization of no apnea (AHI = 0-4.9), mild (AHI = 5-14.9), moderate (AHI = 15-29.9), or severe apnea (AH I> 30).

Methods:

- Data from 11,213 Penn Sleep full-night PSGs (1/06-6/13) were reviewed.
- Total number of apneas-hypopneas, TST (true sleep time), and TRT (total recording time) were used to calculate HST-AHI and PSG-AHI.
- Patients were categorized into no, mild, moderate, and severe apnea by PSG –AHI and HST-AHI. Frequencies of category changes using TST and TRT were analyzed.

Results:

- For 11,213 PSG studies, the mean HST-AHI was 10.7 (SD12.1) and the mean PSG-AHI was 15 (SD17.64).
- For 4564 patients with no apnea by HST-AHI, 81% had no OSA, 18.5% had mild, 0.4% had moderate, and 0.2% had severe OSA by PSG-AHI.
- For 2995 patients with mild apnea by HST-AHI, 70% had mild, 27.4% had moderate, and 2.5% had severe apnea by PSG-AHI.
- For 1898 patients with moderate apnea, 63.2% had moderate and 36.8% had severe OSA.
- All 756 with severe HST-AHI had severe PSG-AHI**.**
- The difference between HST-AHI and PSG-AHI was greater for men ($P < 0.001$ for all calculations).

Conclusion:

- Use of TRT (HST) underestimates apnea and affects treatment options for a significant number of patients. The diagnosis was missed in nearly 20% and underestimated for 27% with mild (HST) apnea and 37% with moderate (HST) apnea. This difference was greater for men.

- Further identifiers will assist in pre-cert for HST and interpretation HST results for OSA cardiac risks and treatment options.

Key Takeaways:

- Lack of TST in most HST devices results in misdiagnosis of 20% subjects.
- The WatchPAT enables assessment of TST, enabling better assessment of OSA severity (similar to in-lab PSG)

AFib

10 Effect of Obstructive Sleep Apnea Treatment on Atrial Fibrillation Recurrence - A meta-analysis

Shukla et al. JACC: Clinical Electrophysiology, 2015. Vol. 1, No. 1-2 *supporting non-WP paper

http://electrophysiology.onlinejacc.org/article.aspx?articleid=2277227

Objective:

- OSA is a known predictor for onset and recurrence of AF. This review was aimed to evaluate the cumulative effect of treatment of Obstructive Sleep Apnea (OSA) with continuous Positive Airway Pressure (CPAP) on Atrial Fibrillation (AF) recurrence.

Methods:

- The authors searched MEDLINE, EMBASE, CINAHL, Google Scholar and the Cochrane Trial Registry for relevant studies.
- Systematic review of 452 relevant citations through June 2014 were identified with 18 potentially relevant articles retrieved. 7 studies were ultimately included in the analysis meeting the predetermined inclusion criteria with a cumulative total of 1,087 patients.
- The primary outcome evaluated AF recurrence in CPAP users and nonusers in patients with OSA.
- The secondary outcome evaluated AF recurrence in CPAP users and nonusers following pulmonary vein isolation (PVI).

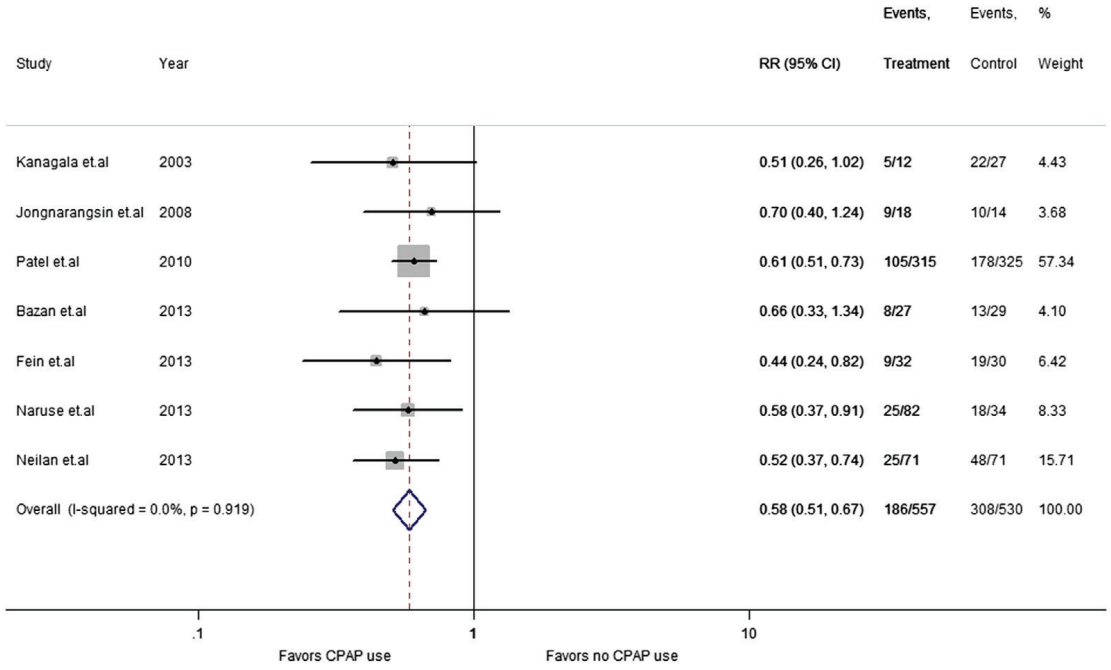
Results:

- Use of CPAP was associated with a significant reduction in AF recurrence (relative risk: 0.58, 95% confidence interval: 0.51 to 0.67; heterogeneity chi-square p = 0.91, I2 = 0%).
- The beneficial effect of CPAP use was statistically significant with both those who underwent catheter ablation with PVI and those who did not undergo ablation and were managed medically.
- No other study covariates had any significant association with these outcomes of AF reduction.

Key Takeaways:

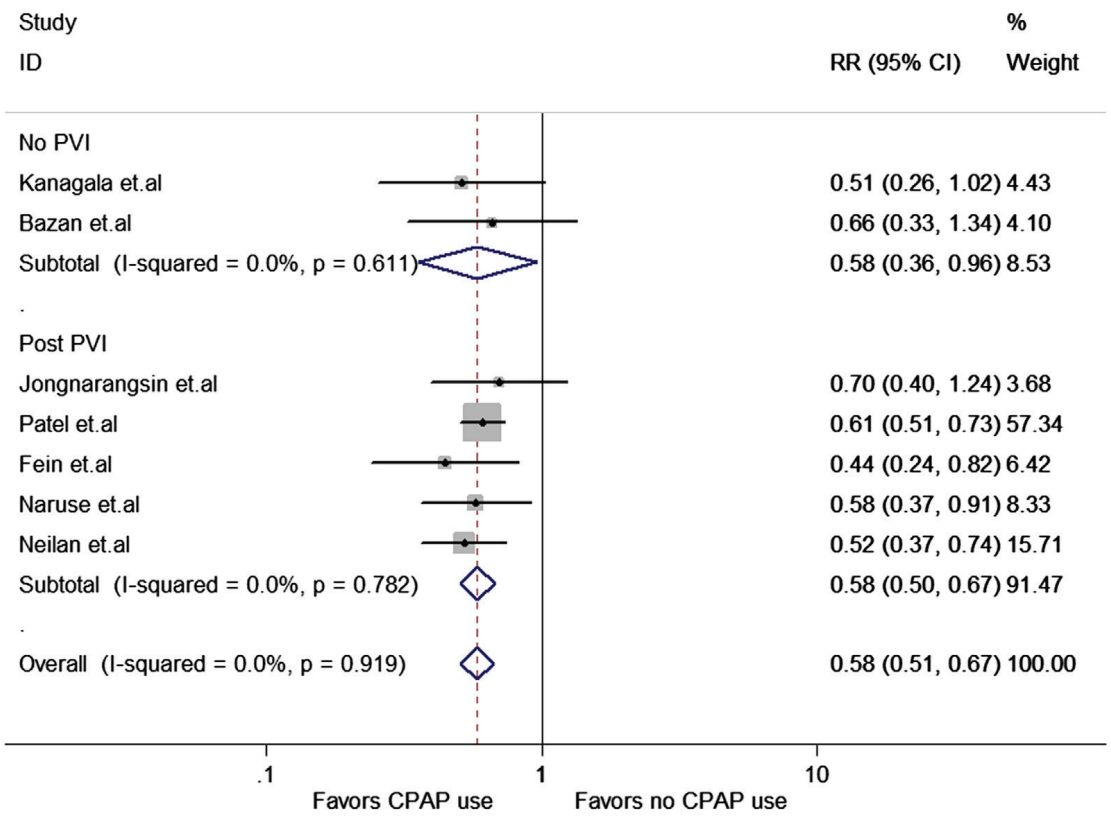
- The use of CPAP is associated with a 42% relative risk reduction in AF recurrence in patients with OSA
- This reduction of AF recurrence appears to be independent of medical or catheter ablation therapy and is consistent across patient groups with OSA.
- These results advocate for active screening for undiagnosed OSA in patients with AF when OSA is clinically suspected.

FIGURE 2 Forest Plot to Compare AF Recurrence in Users Versus Nonusers of CPAP In Patients With OSA



The forest plot exhibits effect size of each included study **(solid box)** with 95% confidence interval (CI) **(black lines through solid squares)**. The **diamond (and broken vertical line)** at the bottom represents pooled summary estimate with its CI given by its width. AF = atrial fibrillation; CPAP = continuous positive airway pressure; OSA = obstructive sleep apnea; RR = relative risk ratio.

FIGURE 3 AF Recurrence in Users Versus Nonusers of CPAP in 2 Groups of Patients With OSA: PVI and Non-PVI Groups



PVI = pulmonary vein isolation; other abbreviations as in Figure 2.

AFib

11 Treatment of Obstructive Sleep Apnea Reduces the Risk of Atrial Fibrillation Recurrence After Catheter Ablation

Fein et al., J Am Coll Cardiol. 2013;62(4):300-305. doi:10.1016/j.jacc.2013.03

http://content.onlinejacc.org/article.aspx?articleid=1685125

*supporting non-WP paper

Objective:

- OSA is a predictor of AF recurrence following PVI. The impact of CPAP therapy on PVI outcome in patients with OSA is poorly known. The aim of the study was to examine the effect of Continuous Positive Airway Pressure (CPAP) therapy on Atrial Fibrillation (AF) recurrence in patients with Obstructive Sleep Apnea (OSA) undergoing Pulmonary Vein Isolation (PVI).

Methods:

- Retrospective study assessing a database of 426 patients who underwent PVI between 2007 and 2010, 62 patients had a polysomnography-confirmed diagnosis of OSA. Of these, 32 patients were "CPAP users" the remaining 30 patients were "CPAP nonusers."
- The recurrence of any atrial tachyarrhythmia, use of antiarrhythmic drugs, and need for repeat ablations were compared between the groups during a follow-up period of 12 months.
- The Control group included a group of patients from the same PVI cohort without OSA and a cohort of 22 OSA patients using CPAP whose AF was treated medically by either electrical cardioversion and/or antiarrhythmic drug therapy.

Results:

- CPAP therapy resulted in higher AF-free survival rate (71.9% vs. 36.7%; $p = 0.01$) and AF-free survival off antiarrhythmic drugs or repeat ablation following PVI (65.6% vs. 33.3%; $p = 0.02$).
- AF recurrence rate of CPAP-treated patients was similar to a group of patients without OSA (HR: 0.7, $p = 0.46$).
- AF recurrence following PVI in CPAP non-user patients was significantly higher (HR: 2.4, $p < 0.02$) and similar to that of OSA patients managed medically without ablation (HR: 2.1, $p = 0.68$).

Conclusion:

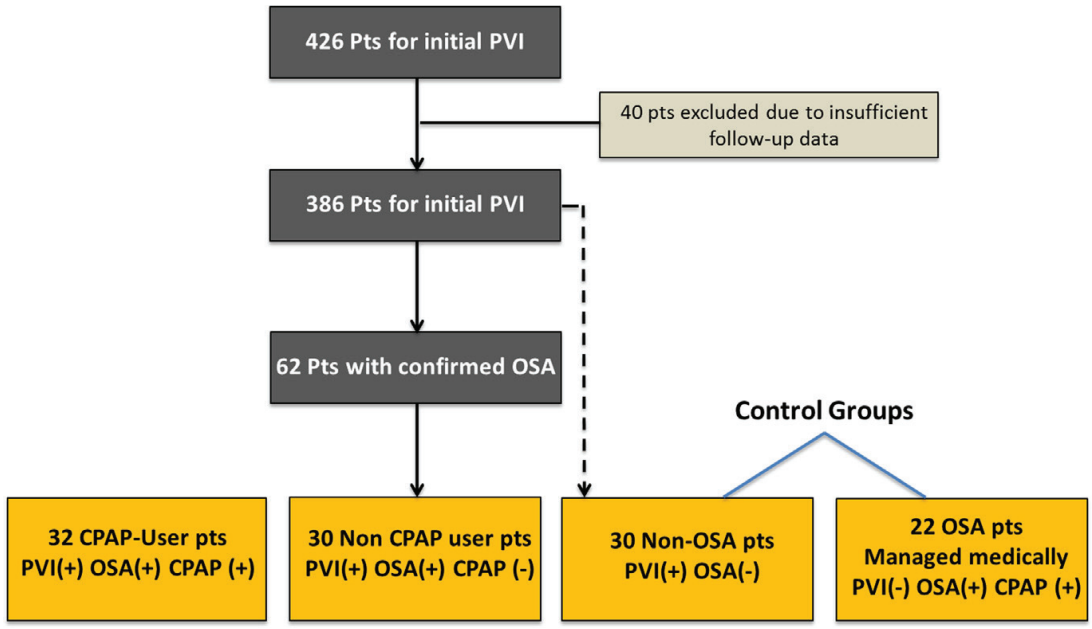
- CPAP therapy in OSA patients undergoing PVI may improve ablation outcome.
- PVI offers limited value to OSA patients not treated with CPAP.

- Careful attention should be paid to screening patients for OSA before PVI in addition to assessing CPAP compliance.

Key Takeaways:

- These results advocate for active screening for undiagnosed OSA in patients with AF when OSA is clinically suspected.
- PVI success rate of AF patients with OSA treated with CPAP is similar to that of AF patients with no OSA

Figure 1:
Flow diagram showing the establishment of the study cohort and division into treatment groups (shown in dark gray and control groups in light gray).



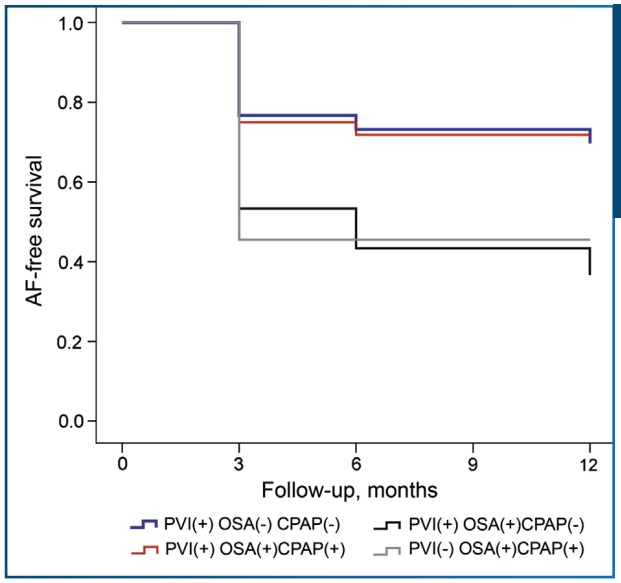


Figure 2:
Kaplan-Meier Survival Curves According to Treatment Group
Log-rank p = 0.02. AF = atrial fibrillation; other abbreviations as in Figure 1.

AFib

12 Effect of Sleep Apnea and Continuous Positive Airway Pressure on Cardiac Structure and Recurrence of Atrial Fibrillation

Neilan, et al. J Am Heart Assoc. 2013;2:e000421

http://jaha.ahajournals.org/content/2/6/e000421.short

*supporting non-WP paper

Objective:

- To determine the effect of Sleep Apnea (SA) on cardiac structure in patients with Atrial Fibrillation (AF).
- To evaluate whether therapy for SA was associated with beneficial cardiac structural remodelling
- Assess whether beneficial cardiac structural remodelling reduces risk of recurrence of AF after Pulmonary Venous Isolation (PVI).

Methods:

- A consecutive group of 720 patients underwent a cardiac magnetic resonance study before PVI.
- The presence or absence of SA was prospectively determined before PVI with the use of a standardized questionnaire administered to all patients.
- All patients diagnosed with SA underwent a formal sleep study.
- The diagnosis of SA was established in accordance with the sleep study criteria recommended by the American Academy of Sleep Medicine.
- Treated SA was defined as duration of continuous positive airway pressure therapy of >4 hours per night.

Results:

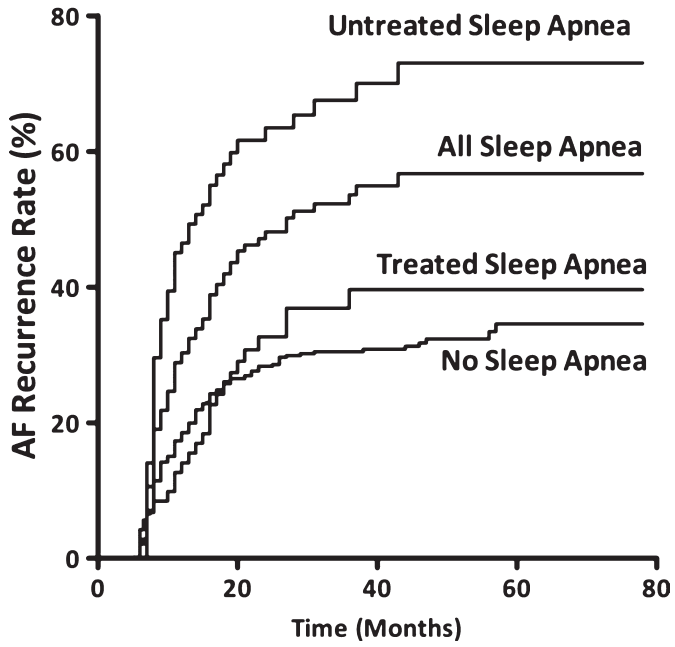
- Patients with SA (n=142, 20%) were more likely to be male, diabetic, hypertensive and have an increased pulmonary artery pressure, right ventricular volume, atrial dimensions, and left ventricular mass. Treated SA patients (n=71, 50%) were more likely to have paroxysmal AF, a lower blood pressure, lower ventricular mass, and smaller left atrium.
- During a follow- up of 42 months, AF recurred in 245 patients.
- The cumulative incidence of AF recurrence was 51% in patients with SA, 30% in patients without SA, 68% in patients with untreated SA, and 35% in patients with treated SA.
- In a multivariable model, the presence of SA (hazard ratio 2.79, CI 1.97 to 3.94, P<0.0001) and untreated SA (hazard ratio 1.61, CI 1.35 to 1.92, P<0.0001) was highly associated with AF recurrence.

Conclusion:

- Patients with SA have an increased blood pressure, Pulmonary Artery Pressure, right ventricular volume, left atrial size, and left ventricular mass.
- PVI offers limited value to OSA patients not treated with CPAP.
- Therapy with continuous positive airway pressure is associated with lower blood pressure, atrial size, and ventricular mass, and a lower risk of AF recurrence after PVI.

Key Takeaways:

- Assessment for SA in symptomatic patients before PVI may improve PVI outcome
- Early assessment of OSA may reduce cardiac structural modification
- Patients identified with structural cardiac modifications and are symptomatic for OSA,



Probability of AF recurrence according to the both the presence of absence of SA, and according to the SA treatment group.

Therapeutics

13 Follow-up Assessment of CPAP Efficacy in Patients with Obstructive Sleep Apnea Using an Ambulatory Device Based on Peripheral Arterial Tonometry

Pittman et al., Sleep Breath (2006) 10: 123–131
http://link.springer.com/article/10.1007%2Fs11325-006-0058-x

Objective:

- To assess the accuracy of PAT technology using the WatchPAT for detecting residual episodes of respiratory disturbance during Continuous Positive Airway Pressure (CPAP) therapy.

Methods:

- 70 patients using CPAP to treat Obstructive Sleep Apnea (OSA) for at least 3 months, who underwent an in-lab titration to determine the optimal therapeutic positive airway pressure, participated in this study.
- Symptoms indicating suboptimal therapy were not required for participation, but self-reported adherence to CPAP therapy was necessary for inclusion.
- The study was conducted in three sleep laboratories affiliated with tertiary care academic medical centers.
- Simultaneous in-lab PSG and WatchPAT recording were performed.
- PSG was used as the reference standard to identify sleep disordered breathing (SDB) events.

Results:

- Based on the PSG results, using Chicago criteria for assessing RDI (RDI.C), 19% of the participants had moderate-severe SDB (PSG RDI.C>15 events per hour) on their prescribed pressure.
- For PAT RDI >15, the area under the ROC curve was 0.95 (SE 0.03, $p < 0.0001$, 95% CI 0.89 to 1.00), the LR+ was 8.04 (95% CI 3.64-17.7), and the LR- was 0.17 (95% CI 0.05-0.62).
- The mean difference between the PAT RDI and PSG RDI.C was 3 events per hour (2SD 14.5).

Conclusion:

- Residual moderate-severe SDB on CPAP was not uncommon in a multicenter population, self-reporting adherence to CPAP therapy

- The WatchPAT device accurately identified participants with residual moderate-severe SDB while using CPAP in the attended setting of a sleep laboratory.

Key Takeaways:

- The WatchPAT is a feasible HST for the evaluation of residual OSA in patients treated with CPAP.
- Patients using CPAP therapy should be evaluated periodically for assessment of residual OSAon
- This study included subjects who self-reported low adherence to CPAP; it did not include subjects based on symptoms. It is safe to assume that had symptomatic subjects been included too, the rate of patients with suboptimal CPAP titration values and residual OSA would increase, further emphasizing the urgency for assessing patient periodically.

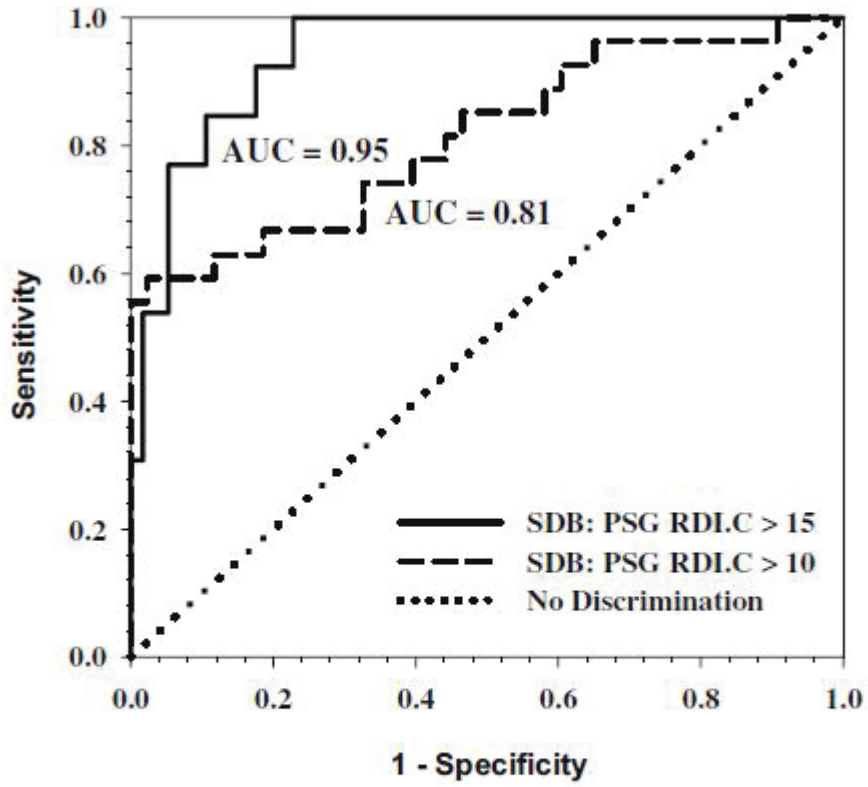


Fig. 3 Receiver–operator characteristic (ROC) curves for discriminating subjects with SDB from those without SDB using the PAT RDI. SDB was defined by the PSG RDI.C with either a threshold of 10 or 15 events per hour of sleep. The area under the curve (AUC) was greater when using the AASM criteria of 15 events per hour to identify moderate–severe SDB

CPAP Therapeutics

14 Portable Monitoring and Autotitration versus Polysomnography for the Diagnosis and Treatment of Sleep Apnea

Berry et al., Sleep. 2008 Oct; 31(10):1423-31

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2572748/

Objective:

- To compare a clinical pathway using portable monitoring (PM) for diagnosis and unattended Autotitration of Positive Airway Pressure (APAP), for selecting an effective Continuous Positive Airway Pressure (CPAP), with a pathway using PSG for diagnosis and treatment of Obstructive Sleep Apnea (OSA).

Methods:

- 106 patients with daytime sleepiness and a high likelihood of having OSA were randomized to the PSG pathway or the PM–APAP pathway.

Results:

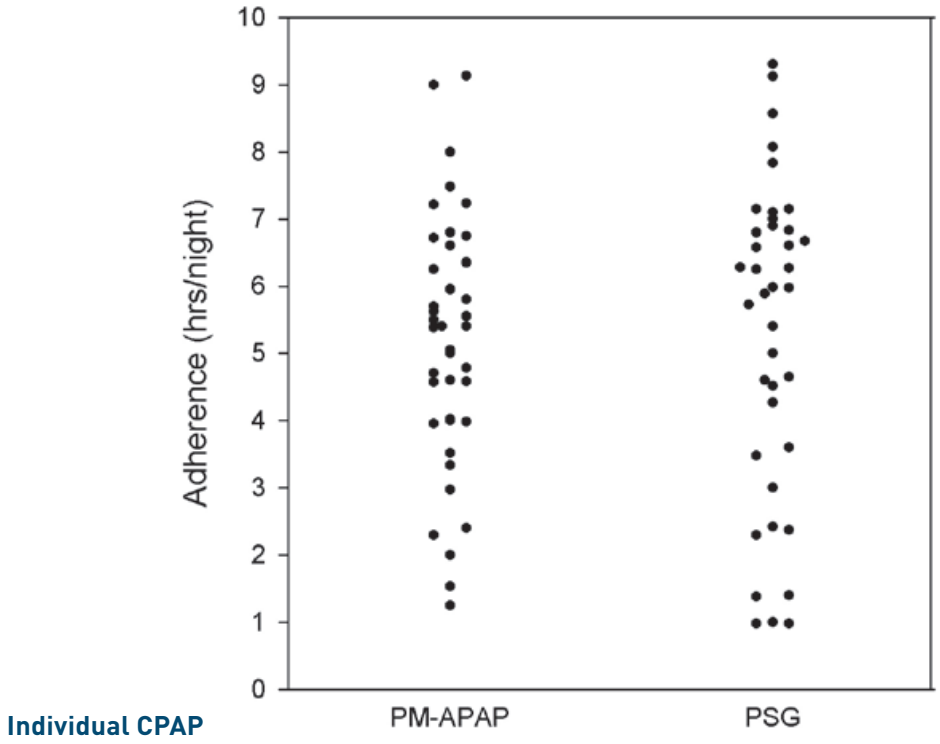
- The AHI in the PM-APAP group was 29.2 ± 2.3/h and in the PSG group was 36.8 ± 4.8/h (P = NS).
- Patients with an AHI > 5 were offered CPAP treatment. Those accepting treatment (PM-APAP 45, PSG 43) were begun on CPAP using identical devices at similar mean pressures (11.2 ± 0.4 versus 10.9 ± 0.5 cm H2O).
- At a clinic visit 6 weeks after starting CPAP, 40 patients in the PM-APAP group (78.4% of those with OSA and 88.8% started on CPAP) and 39 in the PSG arm (81.2% of those with OSA and 90.6% of those started on CPAP) were using CPAP treatment (P = NS).
- The mean nightly adherence (PM-APAP: 5.20 ± 0.28 versus PSG: 5.25 ± 0.38 h/night), decrease in Epworth Sleepiness Scale score (–6.50 ± 0.71 versus –6.97 ± 0.73), improvement in the global Functional Outcome of Sleep Questionnaire score (3.10 ± 0.05 versus 3.31 ± 0.52), and CPAP satisfaction did not differ between the groups.

Conclusion:

- A clinical pathway utilizing PM and WatchPAT APAP titration resulted in CPAP adherence and clinical outcomes similar to one using PSG.

Key Takeaways:

- The WatchPAT can be used for the full cycle of diagnosing and treating OSA.
- This is a perfect option for remote areas, where sleep centres are few or in large medical facilities where waiting lists delay assessment and treatment of OSA.



Individual CPAP **adherence**

values (all nights) are shown for the PM-APAP and PSG study arms

Table 4—Treatment Outcomes

	PM-APAP	PSG	P
Change in ESS	−6.50 ± 0.71	−6.97 ± 0.73	NS
Change in FOSQ	3.10 ± 0.05	3.31 ± 0.52	NS
CPAP satisfaction Questionnaire (3-15), 15 most satisfied	12.8 ± 0.4	12.2 ± 0.2	NS
Machine estimate of residual AHI (/hour)	3.5 ± 0.3	5.3 ± 0.7	NS

Transportation

15 Reliability of the WatchPAT 200 in Detecting Sleep Apnea in Highway Bus Drivers

Yuceege et al., J Clin Sleep Med. 2013 Apr 15; 9(4): 339–344
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3601312/

Objective:

- To assess the validity THE WatchPAT device for diagnosing Sleep Disordered Breathing (SDB) among highway bus drivers.

Methods:

- 90 highway bus drivers underwent PSG and WatchPAT tests simultaneously.

Results:

- The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were 89.1%, 76.9%, 82% and 85.7% for RDI > 15, respectively.
- WatchPAT RDI, ODI, mean SaO2 and SaO2< 90% duration results were well correlated with PSG results.
- In sensitivity and specificity analysis, for cut-off values of RDI of 5, 10 and 15, AUC were 0.84, 0.87 and 0.91, respectively.
- There were no statistically significant differences between total sleep times, nREM and REM durations, and PSG stages1+2 vs. WatchPAT light sleep, but PSG stage 3 was significantly different to WatchPAT deep.

Conclusion:

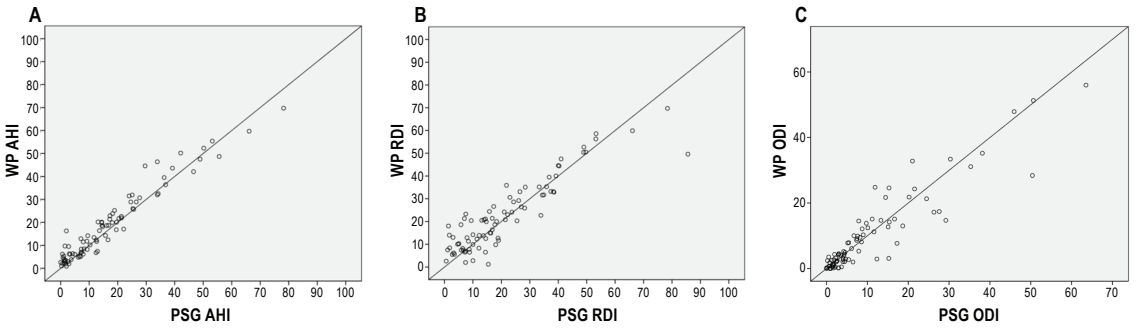
- WatchPAT device is helpful in detecting SDB with RDI > 15 in highway bus drivers, especially in drivers older than 45 years, but has limited value in drivers younger than 45 years old who have less risk for OSA. Therefore, WatchPAT can be used in the former group when PSG is not easily available.

Key Takeaways:

- This study does not discuss the tamper proof bracelet, which is an additional advantage for testing these populations with the WatchPAT
- The WatchPAT can be used in a wide range of professions that require assessment of OSA.
- The long waiting lists, high cost and the inconvenience of spending a night in a sleep

lab can make the WatchPAT an attractive option.

Figure 1—Scatter plots



(A) AHI, (b) RDI, and (C) ODI recorded by PSG and WP. Pearson correlation coeffi cients were 0.96, 0.90, and 0.92, respectively ($p < 0.001$ for all).

Dental & ENT

16 Cardiovascular Benefits of Oral Appliance Therapy in Obstructive Sleep Apnea: A Systematic Review

Van Haesendonck, el al., Journal of Dental Sleep Medicine. Vol. 2, No.1, 2015. 9-14
http://www.jdsm.org/ViewArticle.aspx?pid=29852

*supporting non-WP paper - EndoPAT was used in this study

Objective:

- To perform a systematic review of the current evidence regarding the cardiovascular benefits of Oral Appliance (OA) therapy in Obstructive Sleep Apnea (OSA) patients.

Methods:

- A systematic review of relevant articles retrieved from online databases (PubMed, Web of Science, Medline, OvidSP) was conducted.
- Review included all relevant studies published prior to January 20, 2013 that examined the effects of OA on any of the cardiovascular parameters.

Results:

- OA therapy could have a beneficial effect on blood pressure (BP), Endothelial Function (EF), and left ventricular (LV) cardiac function.
- Eleven articles were included in this systematic review; 7 of 8 studies showed a significant reduction in BP with a mean BP decrease of 4.2 mm Hg, 2 studies showed significant improvement in EF, and 1 study showed significant improvement in LV heart function.

Conclusion:

- OA therapy showed beneficial effects on the cardiovascular comorbidity in OSA patients. In studies comparing OA to CPAP therapy, effects of OA therapy were in the same order of magnitude as the effect of CPAP therapy.

Key Takeaways:

- Dentists are first line identifiers of subjects with suspected OSA and can be key players in OSA treatment.
- Dentists should be "educated" about the possible benefits of OA on the cardiovascular system.

- OA can be a significant revenue generator for dentists.
- The WatchPAT can also be used for assessment and follow-up of OA treatment

Table 2—Summary of OAm treatment studies assessing blood pressure parameters.

Study	Year	N	Age (mean ± SD)	% Male (N)	BMI (mean ± SD)	Duration of intervention	Method of BP measurement	Mean SBP change (mm HG)	Study Type	Pre AHI/h (mean ± SD)	Post AHI/h (mean ± SD)	Δ%
Gotsopoulos et al.[29]	2004	61	48 ± 11	79% (53)	28 ± 5	4 weeks	24-h	−3	RCT	28 ± 17	12 ± 2	57%
Barnes et al.[31]	2004	114	46	79% (67)	31	12 weeks	24-h	0	RCT	21 ± 11	14 ± 10	34%
Yoshida et al.[32]	2006	161	54 ± 14	75% (121)	25 ± 4	15 weeks	Clinical	−5	case series	18 ± 14	6 ± 6	68%
Otsuka et al.[33]	2006	11	52 ± 7	73% (8)	29 ± 4	32 weeks	20-h	−5	case series	25 ± 20	6 ± 4	75%
Andrén et al.[34]	2009	29	57	62% (18)	29 ± 4	3 years	Clinical	−14	case series	16 ± 9	4 ± 3	75%
Andrén et al.[35]	2013	72	58 ± 8	79% (57)	29 ± 4	3 months	24-h	−2	RCT	23 ± 16	8 ± 6	66%
Lam et al.[36]	2007	34	45	76% (26)	27	10 weeks	Clinical	−1	case series	21 ± 10	11 ± 10	49%
Phillips et al.[25]	2013	108	49 ± 11	81% (87)	29 ± 5	1 month	24-h	−2	RCT	26 ± 12	11 ± 12	56%

SD, standard deviation; 24-h (or 20-h), automatic BP measurement during 24 hours a day (or 20 h); Clinical, BP measurement manual or electric; BMI, body mass index (kg/m2); AHI, apnea-hypopnea index; RCT, randomized controlled trial.

Dental & ENT

17 Clinical Usefulness of Watch-PAT for Assessing the Surgical Results of Obstructive Sleep Apnea Syndrome

Park et al., J Clin Sleep Med. 2014 Jan 15;10(1):43-7
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3869067/

Objective:

- To assess the accuracy and clinical efficacy of WatchPAT in evaluating the outcome of sleep surgeries such as septoplasty, tonsillectomy, or uvuloplasty.

Methods:

- Patient population: 35 patients diagnosed with OSA who underwent sleep surgeries such as septoplasty, tonsillectomy, or uvuloplasty for correction of their airway collapse.
- WatchPAT-derived respiratory disturbance index (RDI), apnea and hypopnea index (AHI), lowest oxygen saturation, and valid sleep time were measured before and after surgery.

Results:

- RDI, AHI, lowest oxygen saturation, and valid sleep time recovered to within normal range after surgery in 28 subjects.
- Good agreement was found between WatchPAT-derived factors and visual analogue scales for changes in subjective symptoms (snoring, apnea, and daytime somnolence).
- In 7/35 patients who showed no improvement for their subjective symptoms after surgery, RDI and AHI were not reduced and lowest oxygen saturation and valid sleep time were not elevated.

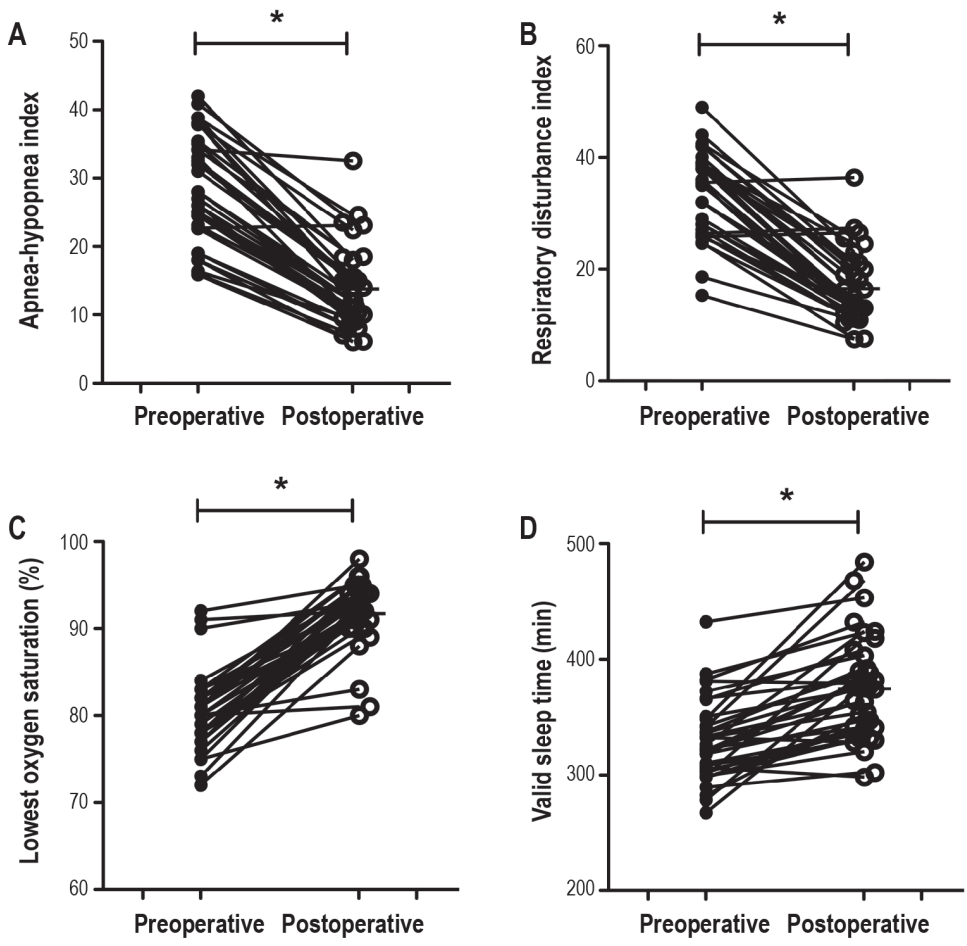
Conclusion:

- WatchPAT is a highly sensitive portable device for estimating treatment results and symptomatic changes in OSA patients after sleep surgery for correction of airway collapse.
- This study demonstrates that the WatchPAT may be efficiently applied not only to the diagnosis of OSA, but also to accurately assess treatment results of sleep surgeries.

Key Takeaways:

- The WatchPAT is a feasible option for ENT doctors for assessing sleep surgery outcome.
- The WatchPAT is easy to use for home sleep studies, with a low failure rate and minimal technical effort.

- The results of watchPAT can be interpreted more simply than full PSG and provide useful information about the efficacy of sleep surgeries.



Change in WatchPAT-derived factors, such as AHI (A), RDI (B), low oxygen saturation (C), and valid sleep time (D), before and after sleep surgery (*p < 0.05 when compared with the levels between preoperative and postoperative)

Dental & ENT

18 Diagnosis or Obstructive Sleep Apnea by Peripheral Arterial Tonometry (Meta - analysis)

Yalamanchali et al. JAMA Otolaryngol Head Neck Surg, 2013.5338
http://www.ncbi.nlm.nih.gov/pubmed/24158564

Objective:

- To assess the correlation between sleep indexes measured by the WatchPAT device and those measured by the PSG.

Methods:

- Review incl. 14 studies (909 patients) with data suitable for pooling that assessed correlation of the respiratory disturbance index (RDI), apnea-hypopnea index (AHI), and oxygen desaturation index (ODI).
- The studies were reviewed by 2 independent reviewers in a systematic manner.

Results:

- WatchPAT and PSG indices of RDI, AHI and ODI, were all significantly correlated with r values of 0.879 (RDI), 0.893 (AHI), and 0.942 (ODI) (all P 0.001). RDI combined with AHI were highly correlated (r = 0.889, p < .001).
- Analysis of publication bias revealed a non-significant Egger regression intercept.

Conclusion:

- Respiratory indices determined by WatchPAT positively correlated with those of PSG strengthened by the blinded design of 13/14 of the included studies. WatchPAT represents a viable alternative to PSG for confirmation of clinically suspected sleep apnea.

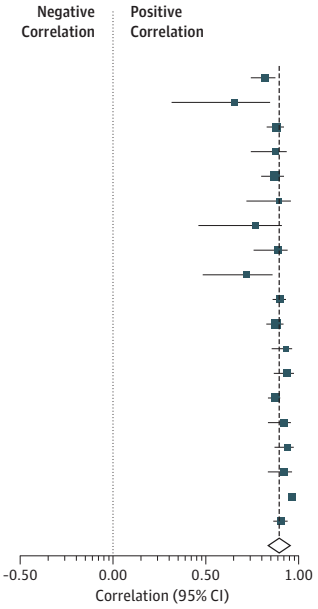
Key Takeaways:

- Compared with PSG, the WatchPAT HST offers an accurate diagnosis, is highly convenient and low cost.
- WatchPAT consistently demonstrated a high degree of correlation in sleep variables when compared to PSG.
- The WatchPAT device is well validated in various countries, patient populations, both in attended in-lab and unattended home settings, by highly valued sleep centers.

- PAT technology is relatively unknown to the otolaryngology community, making this meta-analysis important because it presents a viable option for the diagnosis and subsequent treatment of OSA.
- Review of correlation values over time-line reveals an improvement since change of WatchPAT analysis in 2006

Overall Correlation of the Respiratory Disturbance Index (RDI) and Apnea-Hypopnea Index (AHI) Between Polysomonography (PSG) and Peripheral Arterial Tonometry (PAT)

Source (Study Setting), (Design)	Subgroup Within Study	Correlation, *r* Value	Statistics: Lower Limit (95% CI)	Statistics: Upper Limit (95% CI)	*Z* Value	*P* Value
Pillar et al,[17] 2000 (L), (B)	AHI[a]	0.820	(0.740-0.877)		11.035	<.001
Penzel et al,[18] 2002 (L), (B)	AHI	0.656	(0.313-0.848)		3.334	.001
Bar et al,[19] 2003 (L), (B)	AHI[a]	0.880	(0.826-0.918)		13.480	<.001
Ayas et al,[20] 2003 (L), (B)	AHI	0.870	(0.742-0.937)		6.927	<.001
Pillar et al,[21] 2003 (L), (B)	AHI[a]	0.870	(0.797-0.918)		10.748	<.001
Penzel et al,[22] 2004 (L), (B)	AHI	0.890	(0.715-0.960)		5.320	<.001
Penzel et al,[22] 2004 (L), (B)	RDI	0.770	(0.459-0.913)		3.818	<.001
Pittman et al,[23] 2004 (L), (B)	AHI[a]	0.880	(0.758-0.943)		7.015	<.001
Pittman et al,[23] 2004 (L), (B)	AHI[a]	0.720	(0.480-0.860)		4.628	<.001
Zou et al,[24] 2006 (H), (B)	AHI	0.900	(0.854-0.932)		14.349	<.001
Zou et al,[24] 2006 (H), (B)	RDI	0.880	(0.826-0.918)		13.409	<.001
Pang et al,[25] 2007 (L), (B)	AHI	0.929	(0.858-0.965)		8.883	<.001
Choi et al,[26] 2010 (L), (NB)	AHI	0.940	(0.867-0.974)		8.152	<.001
Hedner et al,[27] 2011 (L), (B)	RDI	0.870	(0.834-0.898)		19.962	<.001
Onder et al,[30] 2012 (L), (B group 1)	AHI	0.920	(0.835-0.962)		8.102	<.001
Onder et al,[30] 2012 (L), (B group 2)	AHI	0.940	(0.871-0.973)		8.515	<.001
Weimin et al,[32] 2013 (L), (B)	AHI	0.920	(0.833-0.963)		7.945	<.001
Yuceege et al,[31] 2013 (L), (B)	AHI	0.960	(0.939-0.974)		17.621	<.001
Yuceege et al,[31] 2013 (L), (B)	RDI	0.909	(0.863-0.940)		13.780	<.001
Overall		0.889	(0.862-0.911)		24.096	<.001



Calculated overall correlation using the random-effects model. Size of the data marker corresponds to the relative weight assigned in the pooled analysis. B indicates blinded; H, home setting; L, laboratory setting; and NB, non-blinded. Study reported the value as RDI; however, recent American Academy of Sleep Medicine criteria defined the value as AHI.

other / general

Recommendations on OOC testing

19 Obstructive Sleep Apnea Devices for Out-Of-Center (OOC) Testing: Technology Evaluation
Collop et al., J Clin Sleep Med 2011;7(5):531-548
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3190855/

Objective:

- Since the classification of portable devices for assessing OSA established in 1994 is out-dated, an AASM taskforce, describes a new classification system for out-of-center (OOC) testing devices for diagnosing OSA.
- To determine a more specific and inclusive method of classifying and evaluating sleep testing devices other than polysomnography (PSG) used in the diagnosis of OSA in the OOC setting.

Methods:

- A series of questions to evaluate the OOC devices was established.
- The task force defined OSA-positive as an AHI > 5.
- To account for the various different output measures provided by the different OOC devices, the task force defined the positive likelihood ratio (LR+) delivered by applying a given test and obtaining a "positive" result. This allows comparisons across a wide variety of devices less sensitive to variations in case definitions.
- Devices were judged on whether or not they can produce an LR+ of at least 5 and a sensitivity of at least 0.825 at an in-lab AHI of at least 5.
- A device categorization scheme that is adaptable, descriptive, and workably specific, was developed based on following measures: Sleep, Cardiovascular, Oximetry, Position, Effort, and Respiratory (SCOPER system).
- A systematic literature search was performed; data on devices were extracted according to standardized methodology. These data were used to categorize the devices according to the SCOPER scheme. Devices that were used in more than 1 configuration have more than 1 SCOPER categorization.

Results:

- Oximetry is mandatory for scoring AHI, a thermistor alone is not adequate, but requires 2 effort belts; nasal pressure can be an adequate measurement of respiration with no effort measure.
- Amongst alternative devices, WatchPAT is deemed adequate, the cardiac signals based device shows promise, but requires more study, the end-tidal CO2 device appears to be adequate for a hospital population, and data is insufficient to determine if acoustic signals in lieu of airflow are adequate to diagnose OSA.

Conclusion:

- Standardized research is needed on OOC devices that report LR+ at the appropriate AHI (5) and scored according to the recommended definitions, while using appropriate research reporting and methodology to minimize bias
- WatchPAT is endorsed by AASM task force.

Key Takeaways:

- The WatchPAT is accepted by the AASM task force, it has 4 of the 6 categories: Sleep, Cardiovascular, Oximetry and Position.

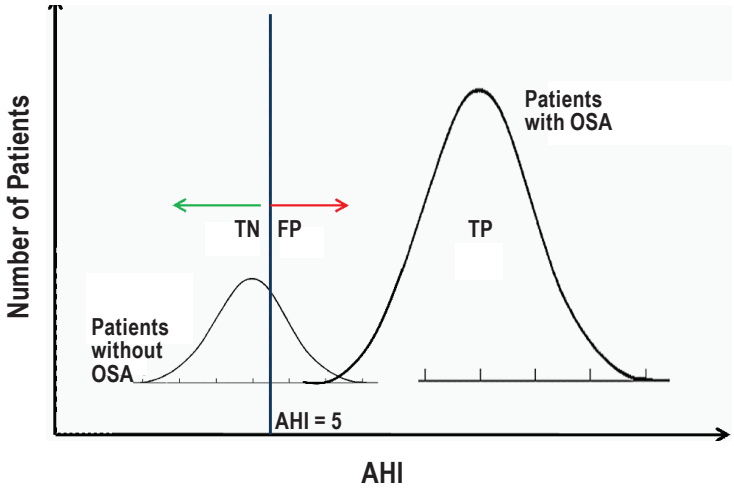


Illustration of the combination of the populations of patients with and without OSA with respect to the AHI cutoff, high pretest probability, true positive, true negative, and false positive results

Table 8—Devices using PAT signal (Watch PAT)

SCOPER/Device/Author (year)	Evidence Level	Setting	LR+	LR-	Sensitivity
$C_2O_{1x}P_2$/Bar et al. (2003)	Ia	L/L	7 at REI/AHI_{ns} ≥ 10*	0.33 at REI/AHI_{ns} ≥ 10*	0.7 at REI/AHI_{ns} ≥ 10*
$S_3C_2O_{1x}P_2$/Zou et al. (2006)	Ia	H/H	9 at REI/AHI_{ns} ≥ 10*	0.11 at REI/AHI_{ns} ≥ 10*	0.9 at REI/AHI_{ns} ≥ 10*
$S_3C_2O_{1x}P_2$/Pang et al. (2007)	Ia	L/L	4.7 at REI/AHI_{ns} ≥ 5	0.075 at REI/AHI_{ns} ≥ 5	0.94 at REI/AHI_{ns} ≥ 5
$S_3C_2O_{1x}P_2$/Pittman et al. (2004)	IIa	L/L	13.0 at REI/AHI_s ≥ 5	0 at REI/AHI_s ≥ 5	0.92 at REI/AHI_s ≥ 5
	IIa	H/L	∞ at REI/AHI_s ≥ 5	0 at REI/AHI_s ≥ 5	1.00 at REI/AHI_s ≥ 5
$S_3C_2O_{1x}P_2$/Pittman et al. (2006)	IIa	L/L	1.6 at REI/AHI_{ns} > 5†	0.29 at REI/AHI_{ns} > 5†	0.86 at REI/AHI_{ns} > 5†
$S_3C_2O_{1x}P_2$/Ayas et al. (2003)	IIa	L/L	2.9 at REI/AHI_{ns} ≥ 10‡	0.24 at REI/AHI_{ns} ≥ 10‡	0.83 at REI/AHI_{ns} ≥ 10‡
$S_3C_2O_{1x}P_2$/Choi et al. (2010)	IIb	L/Hospital	5.9 at REI/AHI_s ≥ 5	0 at REI/AHI_s ≥ 5	1 at REI/AHI_s ≥ 5

*Calculated from original figure in paper at AHIPSG 10 and REIWatchPAT scored according to Chicago criteria. †Scored according to Chicago criteria; if "converted" to standard criteria (see Section 1.0), at REI > 15 the LR+ is 8, which is adequate. Scored according to Chicago criteria; if "converted" to standard criteria (see Section 1.0), at AHI 15 the LR+ is 3.5, which is also inadequate.

other / general

Transition to home monitoring of OSA

20

The Effect of the Transition to Home Monitoring for the Diagnosis of OSAS on Test Availability, Waiting time, Patients' Satisfaction, and Outcome in a Large Health Provider System

Safadi, et al., J Sleep Disorders, Published 24 April 2014

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4020217/

Objective:

- Clalit Health Services (CHS), the largest health insurance provider in Israel, has transitioned from in-lab diagnosis (PSG) of sleep apnea to Home Sleep Test (HST) (WatchPAT by Itamar-Medical, Israel).
- The objective of the paper was to assess the effects of this change on accessibility, waiting time, patient satisfaction, costs, and CPAP purchase by patients.

Methods:

- The study was mostly retrospective, with a small prospective component:
  - Retrospective component: Data was retrieved from a database of 650,000 patients for the following information:
    - Number of sleep studies
    - Number of acquired CPAPs
    - PSG waiting time.
  - Prospective component: Patient satisfaction was assessed utilizing a phone.
- Data comparison was performed between the period of 2007-2008 and period of 2010-2011 (2009 was excluded during the transition from PSG to HST implementation)

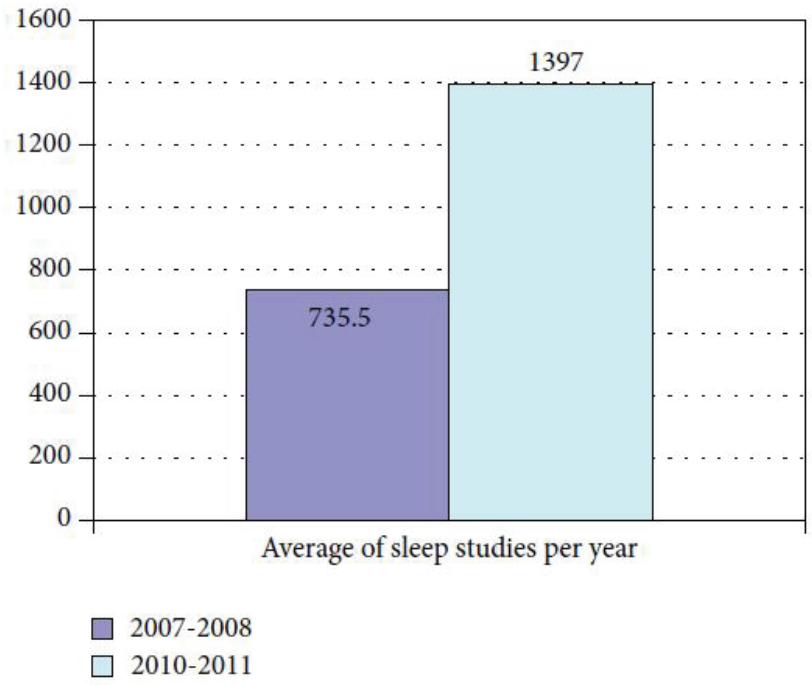
Results:

- 90% increase of sleep study tests following the transition to HST (increase in total insured people during same period was less than 5%)
- Oximetry is mandatory for scoring
- Despite increase in the number of tests, shift to HST was accompanied by over a 20% decrease in overall expense of OSA diagnosis
- Average waiting time decreased significantly from 9.9 weeks during 2007-2008 to just 1.1 week during 2010-2011
- Number of CPAPs purchased in 2007-2008 was 597 devices vs. 831 during 2010-2011 (39% increase)

- Similar outcomes of compliance to CPAP treatment, daily CPAP usage, improvement in daytime sleepiness and quality of life, and patients satisfaction for both home-test and in-lab patients.
- No significant difference in patient satisfaction was reported over the two periods. In retrospect, 56% of patients who underwent in-lab tests and 72% of people who underwent home tests preferred the home sleep test.

Key Takeaways:

- Transition from in-lab testing to unattended home sleep testing has had a positive impact. This stems from improved OSA diagnosis test accessibility, reduced waiting time, reduced overall OSA diagnosis costs and maintained patient satisfaction.



Sleep Disorders 3

TABLE 1: Summary of the patients' satisfaction questionnaires.

Question	Home	Lab-PSG	*P* value
From scale 0 to 10, how uncomfortable was to sleep while being connected to the device? (the higher the result is, the more uncomfortable it is)	2.7	4.1	0.11
How much do you think the study result is true? (0–10)	6.9	7.1	0.84
How much does the diagnostic process influence your decision for treatment? (0–10)	8.9	8	0.14
Estimate your satisfaction from the diagnostic process (0–10)	7.5	8.6	0.2
Do you prefer in-lab or home study? (percent of patients who prefer home study)	72%	56%	0.05*

*$P < 0.05$.

other / general

21 On the Cutting Edge of Obstructive Sleep Apnoea: Where Next?

Malhotra et al., Lancet Respir Med 2015; 3: 397–403 *supporting non-WP paper

http://www.thelancet.com/journals/lanres/article/PIIS2213-2600(15)00051-X/abstract

Objective:

- The rise in prevalence of obstructive sleep apnea is due to multiple factors and more cases coming to the attention of physicians because of the wide availability of diagnostic equipment
- The apnea-hypopnea index (AHI) is an imperfect metric for the definition of obstructive sleep apnea with respect to symptoms and outcomes.
- The purpose of this review is to provide recent insights and discoveries in obstructive sleep apnea, focusing on rapid changes in clinical practice towards novel diagnostics and treatments, establishing a home-based (rather than laboratory-based) management approach and the transition from a so-called "one size fits all" approach to an individualized treatment approach.

Methods:

- Review of peer-reviewed journal articles between January 1 and December 31, 2014 related to obstructive sleep apnea.
- Selection for inclusion was based on the reviewers' expertise and perception of the relevance and impact on the field of sleep medicine.
- Older articles were also included to provide background information and context

Results:

- New data suggests that moderate-to-severe OSA is highly prevalent.
- 90% increase of sleep study.
- OSA might represent a range of diseases rather than a definable cutoff.
- As a result of improved diagnostic technologies, improved therapeutic approaches, and readily available clinical outcome data, today the pathogenesis of OSA is recognized as multifactorial.
- The diagnosis of OSA is transitioning from gold standard polysomnography in sleep laboratories to home sleep testing (HST).
- HST devices that record total sleep time and not only sleep duration are more likely to provide more accurate sleep study results.

- HST devices that reliably track body position are beneficial in diagnosing supine predominant obstructive sleep apnea.
- HST devices that are able to assess wake / sleep as well as sleep stages provide crucial diagnostic data.
- Future work will focus on the causes of Obstructive Sleep Apnea at the individual patient level and therapy will be tailored accordingly.

Key Takeaways:

- The WatchPAT is a HST that matches all the specific criteria mentioned in the review:
    - Measures body position to enable assessing position related OSA
    - TST – for better assessment of OSA (especially mild, moderate cases)
    - Provides REM related OSA diagnosis – for better treatment assessment and better follow up.
    - Provides sleep architecture – to provide impact of OSA on sleep quality.

	Where next?
Epidemiology	
New data suggest that moderate-to-severe OSA is highly prevalent if rigorous methods are used in diagnostic approaches	OSA might represent a range of disease rather than a definable cutoff; public health measures might be needed to increase awareness and to tackle the burden of disease
Pathogenesis	
Non-anatomical traits are important in some patients	Personalised treatment
Diagnostics	
Shift from laboratory-based testing to home sleep testing	Patient initiated testing (ie, smartphone applications)
Ability to measure some physiological traits from clinical polysomnograms	Ability to measure traits from home studies
Outcomes	
Recognition that different sequelae of OSA are important for different outcomes—eg, arousal from sleep affects memory consolidation and 4% oxygen desaturation predicts hypertension	Personalised risk profile
Treatment of OSA in various patient populations—eg, elderly patients have subjective benefit from PAP	Continued understanding of OSA treatment in different patient groups, and specific strategies to improve adherence
Treatments	
Hypoglossal nerve stimulation	Define the role of novel devices
PAP is superior to oxygen therapy for blood pressure reduction	Comparative efficacy research
Substantial reductions in blood pressure with medical weight loss	Optimise strategies for medical and surgical weight loss and weight maintenance

OSA=obstructive sleep apnoea. PAP=positive airway pressure.

Table: **Recent developments in obstructive sleep apnoea**

WatchPAT™

Clinical Compendium
Mar 2017

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