Using a Wrist-Worn Device Based on Peripheral Arterial Tonometry to Diagnose Obstructive Sleep Apnea: In-Laboratory and Ambulatory Validation

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Study Objectives: To assess the accuracy of a wrist-worn device (Watch_PAT 100) to diagnose obstructive sleep apnea in the home.

Design: Participants completed 2 overnight diagnostic studies with the test device: 1 night in the laboratory with concurrent polysomnography and 1 night in the home with only the Watch_PAT. The order of the laboratory and home study nights was random. The frequency of respiratory events on the PSG was quantified using indexes based on 2 definitions of hypopnea: the respiratory disturbance index (RDI) using American Academy of Sleep Medicine Task Force criteria for clinical research, also referred to as the Chicago criteria (RDI.C), and the Medicare guidelines (RDI.M). The Watch_PAT RDI (PAT RDI) and oxygen desaturation index (PAT ODI) were then evaluated against the polysomnography RDI.C and RDI.M, respectively, for both Watch_PAT diagnostic nights, yielding IN-LAB and HOME-LAB comparisons.

Setting: Sleep laboratory affiliated with a tertiary-care academic medical center.

Patients: 30 patients referred with suspected OSA.

Interventions: N/A.

Measurements and Results: The polysomnography and PAT measures were compared using the mean [2 SD] of the differences and the intraclass correlation coefficient (ICC). The receiver-operator characteristic curves were used to assess optimum sensitivity and specificity and calculate likelihood ratios. For the IN-LAB comparison, there was high concordance between RDI.C and PAT RDI (ICC = 0.88, mean difference 2.5 [18.9] events per hour); RDI.M and PAT ODI (ICC = 0.95, mean difference 1.4 [12.9] events per hour); and sleep time (ICC = 0.70, mean difference 7.0 [93.1] minutes) between the test device and PSG. For the HOME-LAB comparison, there was good concordance between RDI.C and PAT RDI (ICC = 0.72, mean difference 1.4 [30.1] events per hour) and RDI.M and PAT ODI (ICC = 0.80, mean difference 1.6 [26.4] events per hour) for the test device and PSG. Home studies were performed with no technical failures.

Conclusions: In a population of patients suspected of having obstructive sleep apnea, the Watch_PAT can quantify an ODI that compares very well with Medicare criteria for defining respiratory events and an RDI that compares favorably with Chicago criteria for defining respiratory events. The device can be used with a low failure rate for single use in the lab and home for self-administered testing.

Citation: Pittman SD; Ayas NT; MacDonald MM et al. Using a wrist-worn device based on peripheral arterial tonometry to diagnose obstructive sleep apnea: in-laboratory and ambulatory validation. SLEEP 2004;27(5):923-33.

INTRODUCTION

OBSTRUCTIVE SLEEP APNEA (OSA) IS A COMMON DISORDER WITH IMPORTANT CLINICAL CONSEQUENCES FOR AFFECTED INDIVIDUALS. Prevalence of the disorder is estimated to be 2% to 4% among a middle-aged population. OSA is characterized by repetitive collapse of the pharyngeal airway during sleep, yielding hypoxia, hypercapnia, and arousal to reestablish airway patency. The associated consequences include daytime sleepiness, decreased cognitive performance, decreased quality of life, increased risk of automobile and industrial accidents, and adverse cardiovascular sequelae. Treatment of OSA leads to improvements in many of these adverse outcomes and may reduce healthcare costs. Thus, diagnosis of this disorder is important.

A commonly used indicator of OSA severity is the respiratory disturbance index (RDI). The RDI represents the total number of apneas and hypopneas per hour of sleep. Most commonly, the RDI is derived primarily from overnight in-laboratory polysomnography (PSG) which includes the continuous recording of many physiologic variables including airflow, chest/abdominal movements, electroencephalography, electrooculography, electromyography, electrocardiography, and oxygen saturation. However, full PSG in the laboratory is expensive, cumbersome, and not readily available in many geographic areas due to a growing demand for the procedure. Although unattended and telemonitored PSG are available, the reliability of these alternatives varies. Gagnadoux and coworkers recently reported a failure rate of 23% for 98 unattended home PSGs even though subjects reported to the laboratory for equipment set up and then returned home for the study. Several investigations of unattended PSG have reported that the majority of subjects preferred in-laboratory PSG over ambulatory PSG.

Calculating RDI with a portable testing device based on a reduced channel set makes diagnosing OSA more feasible in an ambulatory setting such as the home. Ideally, the system is designed for self-administered home use. We and others have...
previously reported on 1 technology that may be useful in the ambulatory diagnosis of OSA, the peripheral arterial tonometer (PAT).\textsuperscript{21-23} This technology uses a finger-mounted pneumo-optical sensor that eliminates venous pulsations and continuously measures the arterial pulse wave volume of the digit. Episodic vasoconstriction of digital vascular beds from sympathetic nervous system activation (mediated by \(\alpha\)-adrenergic receptors) results in attenuation of the signal.\textsuperscript{21} Episodes of upper airway obstruction (eg, apneas, hypopneas) may cause arousal from sleep, sympathetic activation, and peripheral vasoconstriction and can therefore be detected on the PAT signal.\textsuperscript{24}

In the present study, we assessed the accuracy of a wrist-worn device that combines this PAT technology with actigraphy and arterial oxygen saturation to diagnose OSA. Previous studies have assessed the accuracy of this device when compared to simultaneously obtained in-laboratory PSG and have demonstrated good results.\textsuperscript{22,23} This study utilized a similar approach but extended the work of Bar and coworkers by also studying patients in the home where the device is intended to be used.\textsuperscript{22}

**MATERIALS AND METHODS**

**Subjects**

Adult patients referred to the clinical sleep laboratory of Brigham and Women’s Hospital with suspected OSA participated in this study. These participants were not consecutive patients but were a sample of patients who disclosed on a comprehensive questionnaire between June and December of 2002 that they were interested in being contacted about research studies conducted at the sleep laboratory. Exclusion criteria for the study were history of peripheral vascular disease, peripheral neuropathy, nonsinus cardiac rhythm, permanent pacemaker, severe lung disease, status-post bilateral cervical or thoracic sympathectomy, finger deformity that precluded adequate sensor application, and use of \(\alpha\)-adrenergic receptor-blocking agents (24-hour washout period required). Informed consent was obtained from all participants after the protocol was approved by the Human Research Committee of Brigham and Women’s Hospital.

**Protocol**

All subjects completed a comprehensive sleep and health survey that included an Epworth Sleepiness Scale.\textsuperscript{25} Subjects underwent 2 separate evaluations of the home monitoring system (Watch\_PAT 100, Itamar Medical Ltd., Caesarea, Israel): an in-laboratory comparison (IN-LAB) where subjects simultaneously wore the Watch\_PAT during a full-night standard PSG and a home-laboratory (HOME-LAB) comparison during which Watch\_PAT data acquired in the home were compared to PSG results obtained in the laboratory. The order of these 2 nights was random. The home and laboratory studies were scheduled to occur within 1 week of each other, thus avoiding the confounding influence of long time delays between studies.

**Home Sleep Evaluation**

For the home study, subjects reported to the sleep laboratory on the day of their study to receive instruction on the use of the Watch\_PAT device. Instruction addressed proper application of the device and subject demonstration of correct use. This process required 5 to 10 minutes. The Watch\_PAT device was then provided to the subject for transport to their home.

The Watch\_PAT system has been described elsewhere\textsuperscript{22, 21} but consists of a battery-powered, wrist-mounted, recording device and software for postacquisition viewing and analysis of the recorded data. The wrist unit contains an actigraph (3-axis accelerometer for limb movement detection) to differentiate wake time from sleep time. It also includes 2 finger-mounted sensors: a PAT probe (Itamar Medical Ltd., Caesarea, Israel) and a pulse oximeter sensor (Nonin 8000J, Plymouth, Minn). The PAT probe applies a uniform pressure field over the distal two thirds of the finger, including the fingertip, which unloads arterial wall tension without causing distal venous pooling and distension, potential sources of venoarterial-mediated vasoconstriction. A transmission mode photoelectric plethysmograph is used to measure the optical density changes associated with pulsatile blood volume changes in the finger. The Watch\_PAT device records 4 signals: PAT signal (arterial pulse wave volume), heart rate derived from the PAT signal, oxyhemoglobin saturation, and wrist activity (derived from the accelerometer). The device measures the oxyhemoglobin saturation at 1 sample per second from the internal pulse oximeter that uses 4-beat exponential averaging of the raw pulse-wave oxyhemoglobin-saturation measurements (8-beat exponential averaging was used for pulse rates between 112 and 225 beats per minute). The Watch\_PAT device contains a rechargeable power supply, preliminary signal-conditioning hardware, 100-Hz data acquisition, and data storage on a removable COMPACTFLASH disk.

Watch\_PAT studies were uploaded for automated analysis on a personal computer using the COMPACTFLASH reader provided with the PAT software (zzz\_PAT version 2.0.39.13, Itamar Medical Ltd., Caesarea, Israel). The automated analysis used wrist activity to differentiate wake from sleep to determine a PAT valid sleep time (PAT VST) using a proprietary nonstandard algorithm. Respiratory events were detected during segments of PAT VST using a proprietary algorithm developed to match American Academy of Sleep Medicine guidelines for measurement in clinical research (also referred to as “Chicago criteria”).\textsuperscript{26} In particular, a respiratory event was automatically scored if 1 of 3 criteria were met: (1) PAT amplitude reduction occurred with an acceleration in the pulse rate or an increase in wrist activity, (2) PAT amplitude reduction occurred with a 3% or greater oxyhemoglobin desaturation, or (3) a 4% or greater oxyhemoglobin desaturation. The algorithm was developed using previous Watch\_PAT data collected concurrently with PSG data to optimize event-by-event agreement. Oxyhemoglobin desaturations were quantified automatically in a similar fashion. No manual editing of the automated Watch\_PAT scoring was performed. An RDI (PAT RDI) was then reported that represents the number of respiratory events per hour of PAT VST. In addition, an oxygen desaturation index (ODI) was reported that represented the number of oxyhemoglobin desaturations of at least 4% per hour of PAT VST.

**IN-LABORATORY PSG**

All subjects underwent a standard in-laboratory overnight PSG. Signals recorded included electroencephalogram (C4-A1, C3-A2, O2-A1 and O1-A2), electrooculogram, submental and bilateral tibial electromyogram, electrocardiogram, airflow...
The utility and accuracy of the Watch_PAT indexes in detecting OSA was based on summary data for both nights (laboratory and home) and was evaluated in a number of ways. These included evaluations for concordance using intraclass correlation (ICC: model 2, individual ratings), agreement using the method of Bland and Altman, and by constructing receiver operating characteristic (ROC) curves (Analyse-It Clinical Laboratory Software ver. 1.67, Leeds, England) using RDI.M and RDI.C cutoffs of 5, 10, 20, and 30 events per hour. Given that there is no well-defined RDI cutoff value for defining OSA, we also assessed diagnostic agreement using a clinical approach described previously to assess the diagnostic utility of another ambulatory device to detect OSA.

According to this analysis, the Watch_PAT and PSG are considered in agreement if (1) both the RDI.C and PAT RDI were greater than 40 events per hour or (2) the RDI.C was less than 40 events per hour on PSG and the PAT RDI was within 10 events per hour of the RDI.C.

All results are given as means ± 1 SD except for the means of the differences for the Bland-Altman analyses, which are given as means (± 2 SD for limits of agreement). Statistical significance was considered to be present when P < .05.

RESULTS

We recruited a total of 30 subjects with suspected OSA who met prospective eligibility requirements for participation in this study. Of these participants, 1 subject was excluded because of significant signal artifact on the study night in the sleep laboratory that prevented analysis of the PAT signal. Thus, data from 29 subjects (21 men, 8 women) are included in the analysis. The mean age of these subjects was 43.2 ± 10.8 years and mean body mass index was 33.9 ± 7.1 kg/m². The mean Epworth Sleepiness Scale score was 9.2 ± 4.7 (range 2-18). The mean interval between HOME and IN-LAB studies was 1.7 ± 1.0 days. The IN-LAB was first in 17 (58.6%) subjects.

Validation of the PSG manual scoring of sleep stages yielded epoch-by-epoch agreement of 93.4% (discriminating wake, non-rapid eye movement sleep, and rapid eye movement sleep) with a Cohen κ statistic of 0.86. The agreement was 95.1%, and Cohen κ statistic was 0.83 for the RDL.M calculation between the 2 manual PSG scorers using comparisons of 0, 1, or 2 respiratory events per epoch.

In-Lab Comparison

Chicago Criteria

For the night in the laboratory, mean TST per PSG was 347.4 ± 64.6 minutes, while the mean LAB-PAT VST was 340.3 ± 55.5 minutes (see Table 1). There was good agreement between LAB-PAT VST and PSG TST (ICC = 0.70 mean difference 7.0 [93.1] minutes). Mean RDI.C per PSG was 31.6 ± 20.6 events per hour, while the mean LAB-PAT RDI was 34.2 ± 19.2 events per hour. The LAB-PAT RDI and PSG RDI.C were concordant (ICC = 0.88, Figure 1A). A Bland Altman plot of LAB-PAT RDI and PSG RDI.C is shown in Figure 1B; there was no obvious systematic difference between the 2 variables.

Data Analysis

Sleep studies were considered acceptable for data analysis if none of the following rejection criteria occurred: (1) PSG total sleep time (TST) less than 1.5 hours, (2) Watch_PAT valid sleep time less than 1.5 hours, (3) poor-quality PSG recording (defined as a substantial portion of the PSG being not interpretable to score sleep and respiratory events), or (4) all Watch_PAT channels not available for review and automatic analysis. The PSG was considered the gold standard for identifying and quantifying OSA. The Watch_PAT was compared to respiratory events detected on the PSG using both Chicago and Medicare criteria. Detection of respiratory events using Chicago criteria was assessed by comparing the PAT RDI to the PSG RDL.M. Detection of respiratory events using Medicare criteria was assessed by comparing the PAT ODI to the PSG RDL.M. The manual PSG scoring of sleep stages and respiratory events (Medicare criteria) was validated by assessing agreement between the reference scorer and a second scorer. Epoch-by-epoch comparisons yielded the percentage of epochs with agreement, and Cohen κ statistic measured the chance-corrected level of agreement.

The utility and accuracy of the Watch_PAT indexes in detecting OSA was based on summary data for both nights (laboratory and home) and was evaluated in a number of ways. These included evaluations for concordance using intraclass correlation (ICC: model 2, individual ratings), agreement using the method of Bland and Altman, and by constructing receiver operating characteristic (ROC) curves (Analyse-It Clinical Laboratory Software ver. 1.67, Leeds, England) using RDI.M and RDI.C cutoffs of 5, 10, 20, and 30 events per hour. Given that there is no well-defined RDI cutoff value for defining OSA, we also assessed diagnostic agreement using a clinical approach described previously to assess the diagnostic utility of another ambulatory device to detect OSA.

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SLEEP, Vol. 27, No. 5, 2004

925 Using a Wrist-Worn Device Based on PAT to Diagnose OSA—Pittman et al
We constructed ROC curves to assess the sensitivity and specificity of the Watch_PAT system using a range of PSG RDI.C threshold values (5, 10, 15, 20, and 30 events per hour) to differentiate normal cases from those with OSA. The area under the ROC curves was undefined for a threshold of 5 events per hour, 0.96, 0.89, 0.93, and 0.95, respectively. Optimal combinations of sensitivity and specificity are shown in Table 2. When using the previously described clinical approach to assess agreement, 35 concordance was found in 24 out of 29 subjects (83%). There was substantial disagreement in 1 case (subject #9: mild OSA by Chicago criteria). The PSG RDI.C was 10.8 events per hour in this individual, but the LAB-PAT RDI was 40.6 events per hour. In this individual, the Watch_PAT device seemed to be detecting sympathetic activation associated with events that did not meet the Chicago criteria for scoring hypopneas (see Figure 2). This individual’s score on the Epworth Sleepiness Scale was 16 out of a possible score of 24.

Medicare Criteria

The mean RDI.M per PSG was 18.3 ± 21.9 events per hour, while the mean LAB-PAT ODI was 16.9 ± 19.5 events per hour. There was excellent agreement between LAB-PAT ODI and RDI.M (ICC = 0.95) as is shown in Figure 1C. A Bland Altman plot of LAB-PAT ODI and RDI.M is shown in Figure 1D.

We constructed ROC curves to assess the sensitivity and specificity of the Watch_PAT system using PSG RDI.M threshold values (5, 10, 15, 20, and 30 events per hour) to differentiate normal cases from those with OSA. The area under the ROC curves was 0.99, 1.0, 0.99, 1.0, and 0.99, respectively. Optimal combinations of sensitivity and specificity are shown in Table 3. There was a substantial disagreement for 1 case (subject #3). The PSG RDI.M was 57.6 events per hour in this individual, but the Lab-PAT ODI was 28.3 events per hour. The source of the disagreement was obstructive apneas that met Medicare criteria but did not yield a 4% or greater oxyhemoglobin desaturation. Thus, respiratory events included in the PSG RDI.M were not included in the LAB-PAT ODI. A representative sample from the PSG is shown in Figure 3.

| Table 1—Data for Each Subject Comparing Watch_PAT with Polysomnography |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Subject | ESS score | TST | PSG RDI.M | LAB VST | Watch_PAT ODI | HOME Watch_PAT RDI |
| 1 | 9 | 287.0 | 2.1 | 35.7 | 317.0 | 9.5 | 54.3 | 345.0 | 4.7 | 29.7 |
| 2 | 9 | 353.0 | 3.9 | 11.0 | 378.0 | 2.1 | 19.8 | 400.0 | 1.7 | 11.5 |
| 3 | 4 | 383.5 | 57.6 | 80.3 | 337.0 | 28.3 | 69.9 | 345.0 | 15.1 | 22.7 |
| 4 | 18 | 347.0 | 14.9 | 26.8 | 361.0 | 11.3 | 22.3 | 383.0 | 24.3 | 44.2 |
| 5 | 12 | 327.0 | 8.4 | 23.3 | 319.0 | 7.3 | 21.8 | 345.0 | 4.7 | 29.7 |
| 6 | 10 | 410.0 | 8.0 | 19.8 | 375.0 | 8.0 | 14.2 | 377.0 | 15.1 | 22.7 |
| 7 | 10 | 272.5 | 27.3 | 47.0 | 285.0 | 31.7 | 42.4 | 187.0 | 11.8 | 15.7 |
| 8 | 11 | 343.0 | 78.2 | 82.4 | 339.0 | 72.9 | 74.3 | 266.0 | 71.3 | 73.1 |
| 9 | 16 | 440.5 | 1.1 | 10.8 | 442.0 | 5.3 | 40.6 | 460.0 | 0.8 | 4.7 |
| 10 | 15 | 372.0 | 0.2 | 7.1 | 336.0 | 2.1 | 14.1 | 324.0 | 0.2 | 11.3 |
| 11 | 6 | 344.0 | 1.0 | 10.3 | 321.0 | 0.4 | 15.1 | 388.0 | 0.3 | 11.0 |
| 12 | 3 | 323.0 | 12.6 | 37.9 | 276.0 | 17.0 | 47.8 | 334.0 | 38.4 | 38.4 |
| 13 | 9 | 404.0 | 1.6 | 12.2 | 412.0 | 2.3 | 15.3 | 384.0 | 1.9 | 12.5 |
| 14 | 16 | 373.5 | 3.5 | 12.7 | 327.0 | 3.3 | 12.6 | 398.0 | 2.7 | 10.7 |
| 15 | 3 | 140.5 | 29.0 | 40.1 | 312.0 | 18.6 | 35.7 | 189.0 | 22.5 | 54.5 |
| 16 | 17 | 446.5 | 12.6 | 20.7 | 410.0 | 13.6 | 25.9 | 267.0 | 10.8 | 24.9 |
| 17 | 9 | 413.0 | 14.5 | 28.8 | 459.0 | 17.5 | 45.2 | 424.0 | 24.9 | 54.0 |
| 18 | 7 | 311.5 | 4.2 | 26.5 | 257.0 | 7.0 | 20.1 | 342.0 | 1.2 | 9.1 |
| 19 | 8 | 303.0 | 4.6 | 22.0 | 304.0 | 1.6 | 17.0 | 356.0 | 4.4 | 36.9 |
| 20 | 10 | 340.0 | 65.1 | 69.7 | 341.0 | 62.9 | 75.0 | 335.0 | 30.0 | 44.2 |
| 21 | 12 | 354.0 | 21.7 | 36.3 | 378.0 | 17.6 | 27.7 | 448.0 | 22.3 | 31.6 |
| 22 | 6 | 243.0 | 36.5 | 45.4 | 243.0 | 35.6 | 51.1 | 408.0 | 21.6 | 41.3 |
| 23 | 5 | 381.0 | 19.5 | 37.5 | 288.0 | 14.1 | 25.4 | 240.0 | 46.4 | 59.9 |
| 24 | 17 | 445.5 | 62.5 | 62.5 | 418.0 | 62.2 | 60.4 | 234.0 | 65.6 | 67.9 |
| 25 | 7 | 352.0 | 1.2 | 21.8 | 349.0 | 1.6 | 33.3 | 312.0 | 1.9 | 15.4 |
| 26 | 2 | 305.0 | 27.9 | 38.7 | 309.0 | 23.9 | 48.4 | 354.0 | 24.4 | 51.0 |
| 27 | 8 | 316.0 | 0.6 | 16.3 | 297.0 | 1.8 | 20.6 | 324.0 | 3.0 | 19.3 |
| 28 | 2 | 404.0 | 4.3 | 20.3 | 405.0 | 3.9 | 26.6 | 451.0 | 4.0 | 16.5 |
| 29 | 7 | 340.5 | 4.9 | 13.7 | 275.0 | 5.7 | 14.2 | 367.0 | 2.8 | 7.3 |
| Mean | 9.2 | 347.4 | 18.3 | 31.6 | 340.3 | 16.9 | 34.2 | 344.1 | 16.7 | 30.2 |
| SD | 4.7 | 64.6 | 21.9 | 20.6 | 55.5 | 19.5 | 19.2 | 73.9 | 19.0 | 19.5 |

PSG refers to polysomnography; ESS, Epworth Sleepiness Scale; TST, manually scored total sleep time, in minutes; RDI.M, manual respiratory disturbance index with Medicare criteria per hour of sleep; RDL.C, manually scored respiratory disturbance index with Chicago criteria per hour of sleep; VST, automated valid (estimated) sleep time, in minutes; ODI, automated oxyhemoglobin desaturation (= 4%) index per hour of estimated sleep time; RDI, automated respiratory disturbance index per hour of estimated sleep time. 

Using a Wrist-Worn Device Based on PAT to Diagnose OSA—Pittman et al
No technical failures occurred during the HOME studies, thus data were available for analysis in all 29 subjects. The mean HOME-PAT VST for the HOME studies was 344.1 ± 73.9 minutes. There was not a significant correlation between HOME-PAT VST and PSG TST (Pearson product-moment correlation coefficient = 0.28, \( P = .14 \)). The mean HOME-PAT RDI was 30.2 ± 19.5 events per hour for the home study night. There was good agreement between HOME-PAT RDI and RDI.C (ICC = 0.72, Figure 4A) even though they were recorded on different nights. A Bland Altman plot of HOME-PAT RDI and RDI.C is shown in Figure 4B. With RDI.Cs in the severe range, the HOME-PAT RDI tended to underestimate OSA severity in some cases, although the mean difference between the Home-PAT RDI and RDI.C was only 1.5 events per hour. The night-to-night variability of the PAT RDI in this study (when PAT values in the HOME are compared to PAT values in the lab) is shown in Figure 5A. The ICC for HOME-PAT RDI and LAB-PAT RDI was 0.62.

**Chicago Criteria**

![Graph A](image1.png)

**Medicare Criteria**

![Graph C](image2.png)

**Figure 1**—In-laboratory (Watch_PAT data collected concurrently with polysomnography data) comparisons are shown. (A) Scatter plot of PSG RDI.C vs LAB-PAT RDI with a best-fit line of \( Y = -0.97 + 0.95X \). (B) Bland-Altman plot of PSG RDI.C vs LAB-PAT RDI. Agreement was good except for 1 case, subject #9. (C) Scatter plot of PSG RDI.M vs LAB-PAT ODI with a best-fit line of \( Y = 0.10 + 1.1X \). (D) Bland-Altman plot of PSG RDI.M vs LAB-PAT ODI. Agreement was good except for one case, subject #3. PAT refers to peripheral arterial tonometer; PSG, polysomnography; RDI, respiratory disturbance index; RDI.C, RDI based on American Academy of Sleep Medicine criteria (also known as the Chicago criteria); RDI.M, RDI based on Medicare criteria; ODI, oxygen desaturation index; ICC, intraclass correlation coefficient.
**Table 2— Area Under the ROC Curve; Optimum Sensitivity and Specificity, Likelihood Ratios (Chicago Criteria)**

<table>
<thead>
<tr>
<th>Watch_PAT in LAB</th>
<th>RDI.C</th>
<th>OSA Prev</th>
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ROC refers to receiver operating characteristic; RDI.C, respiratory disturbance index (RDI) from polysomnography (Chicago criteria); OSA Prev, prevalence of obstructive sleep apnea; AUC, area under the ROC Curve; Sens, Sensitivity; Spec, Specificity; Low CI, lower 95% confidence interval; Up CI, upper 95% confidence interval; LR⁺, positive likelihood ratio; LR⁻, negative likelihood ratio; PAT RDI, corresponding peripheral arterial tonometer RDI (based on Watch_PAT derived sleep time); ∞, infinity; ‡, cannot be calculated. Note: An ROC curve could not be generated for an RDI.C threshold of 5 events per hour because the prevalence of OSA was 100% for that value. Thus, the AUC, optimum sensitivity/specificity, and likelihood ratios cannot be calculated.

**Figure 2—** This represents a 3-minute sample from a polysomnogram (subject #9: mild sleep apnea by Chicago criteria). One hypopnea is shown (event indicated by the word Hypopnea in the box). Five respiratory events detected by the Watch_PAT software and included in the peripheral arterial tonometer (PAT) respiratory disturbance index (RDI) are indicated on the electroencephalogram (EEG) channel with the text Resp Event Arousal. No oxyhemoglobin desaturations of 4% were present during this segment of the study. This illustrates a period with 20% agreement when comparing the Watch_PAT RDI to the Chicago criteria for scoring respiratory events, yet there was 100% agreement when comparing the Watch_PAT oxygen desaturation index (ODI) to the Medicare criteria for scoring respiratory events. Thus, due to the sensitivity of the Watch_PAT algorithm to detect sympathetic activation for scoring respiratory events included in the PAT RDI and the absence of an airflow signal to increase specificity, 4 respiratory events were detected by the Watch_PAT device that did not meet Chicago criteria by polysomnography in this individual. However, careful examination of the raw data does indicate sustained periods of snoring and flow limitation on the nasal pressure channel. EMG_AT refers to anterior tibialis electromyography; NP, nasal pressure (surrogate for airflow); Abd, abdominal movement; HR, heart rate; SaO₂, arterial oxyhemoglobin saturation.
Table 3—Area Under the ROC Curve; Optimum Sensitivity and Specificity, Likelihood Ratios (Medicare Criteria)

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ROC refers to receiver operating characteristic; RDI.M, respiratory disturbance index (RDI) from polysomnography (Medicare criteria); OSA Prev, prevalence of obstructive sleep apnea; AUC, area under the ROC Curve; Sens, Sensitivity; Spec, Specificity; Low CI, lower 95% confidence interval; Up CI, upper 95% confidence interval; LR⁺, positive likelihood ratio; LR⁻, negative likelihood ratio; PAT RDI, corresponding peripheral arterial tonometer RDI (based on Watch_PAT derived sleep time); ∞, infinity; ‡, cannot be calculated. Note: An ROC curve could not be generated for an RDI.C threshold of 5 events per hour because the prevalence of OSA was 100% for that value. Thus, the AUC, optimum sensitivity/specificity, and likelihood ratios cannot be calculated.

Figure 3—This represents a 2-minute sample from a polysomnogram (subject #3: severe sleep apnea). Four obstructive apneas are shown (events indicated by the words Apnea Obstructive in the boxes). Respiratory events detected by the Watch_PAT software and included in the peripheral arterial tonometer (PAT) respiratory disturbance index (RDI) are indicated on the electroencephalogram (EEG) channel with the text Resp Event Arousal. An oxyhemoglobin desaturation of 4% detected by the Watch_PAT software and included in the PAT oxygen desaturation index (ODI) is indicated on the arterial oxyhemoglobin saturation (SaO₂) channel with the word Desaturation. This illustrates a period with 100% agreement when comparing the Watch_PAT RDI to the Chicago criteria for scoring respiratory events but only 25% agreement when comparing the Watch_PAT ODI to the Medicare criteria for scoring respiratory events. Thus, due to the lack of Watch_PAT airflow measurement, 3 obstructive events without adequate oxyhemoglobin desaturation were missed based on these less-inclusive criteria. NP prefers to nasal pressure (surrogate for airflow); Abd, abdominal movement; HR, heart rate.
ROC curves were constructed as stated for the laboratory night with various PSG RDI.C threshold values (5, 10, 15, 20, and 30 events per hour) to differentiate normal cases from those with OSA. The area under the ROC curves was undefined for a threshold of 5 events per hour, 0.82, 0.97, 0.92, and 0.89, respectively. Optimal combinations of sensitivity and specificity are shown in Table 2. When using the previously described clinical approach to assess agreement, concordance was found in 21 out of 29 subjects (72%).

Medicare Criteria

The mean PAT ODI was 16.7 ± 17.1 events per hour for the HOME study night. There was good agreement between home-PAT ODI and PSG RDI.M (ICC = 0.80) even though they were recorded on different nights, as shown if Figure 4C. A Bland-Altman plot of HOME-PAT ODI and PSG RDI.M is shown in Figure 4D. The night-to-night variability of the PAT ODI in this study is shown in Figure 5B. The agreement between LAB-PAT ODI and HOME-PAT ODI was good (ICC = 0.83).

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events per hour) differentiating normal cases from those with OSA. The area under the ROC curves was 1.0, 0.99, 0.90, 0.86, and 0.87, respectively. Optimal combinations of sensitivity and specificity are shown in Table 3.

DISCUSSION

In this study, we assessed the diagnostic accuracy of a wrist-worn device to detect OSA with concurrent PSG in the laboratory and when subject-administered in the home. This device is unique in that detection of episodic vasoconstriction of the digital vascular beds contributes to the identification of episodes of upper airway obstruction, rather than conventional measures of airflow and chest movements. The results of the IN-LAB study suggest there is generally good agreement between Watch_PAT and PSG in quantifying apnea plus hypopnea frequency with acceptable sensitivity, specificity, and diagnostic agreement between systems. The LAB-PAT ODI was concordant with the PSG RDI_M (Medicare criteria). The HOME-LAB comparison results suggest that technical failures are rare with use of the Watch_PAT system in the home (0% in this study), but there was less agreement between respiratory events detected with the Watch_PAT in the home and the laboratory PSG.

Validating an ambulatory sleep diagnostic system is challenging due to the lack of a true gold standard in detecting sleep-disordered breathing events during sleep, absence of a well-accepted cutoff in apnea-hypopnea frequency to differentiate normal cases from those with OSA, and night-to-night variability in measures of sleep and respiration that makes home assessment versus laboratory evaluation difficult. These issues will be addressed separately. Detecting apneas and hypopneas during sleep studies is not exact because quantifying airflow with pneumotachometry is not practical for routine use and the transducers that are used to measure respiration are semiquantitative at best. Furthermore, the definition of hypopnea is not consistent from laboratory to laboratory, or even in published guidelines. One definition allows scoring a hypopnea with a noticeable change in airflow terminated by an arousal or a 3% desaturation (RDIC), while another requires at least a 30% reduction in airflow or effort combined with an oxyhemoglobin desaturation of at least 4% to improve the reliability of scoring respiratory events (RDI_M). Published data suggest that manual PSG scoring of hypopneas based on arousal without desaturation is subject to more interscorer variability. We therefore chose to quantify sleep-disordered breathing using both Chicago and Medicare criteria and then compared these indexes to the Watch_PAT RDI and ODI, respectively.

The absence of a clear cutoff in the RDI (Chicago or Medicare criteria) by which sleep apnea can be diagnosed presents significant challenges for calculating the prevalence of OSA and ROC curves that require discrimination of normal from abnormal cases using a gold standard. Thus, we used a variety of cutoffs (5, 10, 15, 20, and 30 events per hour of sleep) to assess discrimination of subjects with OSA from normal cases with the Watch_PAT. A cutoff of 5 events could not be used for the RDI_C analysis because OSA prevalence was 100% in our study population.

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A recent investigation of short-term variability in respiration and sleep during unattended nonlaboratory nights reported no significant bias in RDI between study nights. However, both study nights were in the same environment. Previous investigations report considerable night-to-night variability in measures of RDI. In our study, subjects were studied on different nights with different environments, and we suspect this could be a source of variability in the HOME-LAB comparison. As illustrated in Figure 5A, there was a mean difference of 4.0

![Figure 5](https://example.com/figure5.png)

**Figure 5**—Home-Laboratory (Watch_PAT data collected on different nights) comparisons are shown. (A) Bland-Altman plot of HOME-PAT RDI vs LAB-PAT RDI. (B) Bland-Altman plot of HOME-PAT ODI vs LAB-PAT ODI. PAT refers to peripheral arterial tonometer; PSG polysomnography; RDI, respiratory disturbance index; RDI_C, RDI based on American Academy of Sleep Medicine criteria (also known as the Chicago criteria); ODI, oxygen desaturation index.
events per hour when comparing the HOME-PAT RDI and LAB-PAT RDI with the bias toward larger RDIs in the lab. Therefore, false positives and false negatives encountered in the home may be attributed to night-to-night or home-to-laboratory variability rather than diagnostic inaccuracy of the Watch_PAT system. In spite of the problems described above (no gold standard for respiration assessment, no clear RDI cutoff for apnea diagnosis, and night-to-night variability), we conclude that the Watch_PAT system is producing accurate, clinically interpretable data.

The ASDA has classified sleep diagnostic systems into 4 categories based on the testing environment, technician attendance, and number of parameters recorded. Level I was reserved for in-laboratory PSG. A number of portable sleep diagnostic systems are available, but relatively few have been validated in an unattended home setting. These vary from simple oximetry (ASDA level IV) to complex systems that fully monitor sleep and respiration in the home (ASDA level II). A comprehensive evidence review of the literature on home monitoring for sleep apnea and practice parameters for the use of portable monitoring in the investigation of suspected OSA are available.

Unattended, portable, full PSG performed in the home is considered a level II study by ASDA criteria. Home PSGs have been used for large epidemiology studies but may not be practical for clinical practice due to the requirement of technician set up. Furthermore, there is insufficient evidence to determine the validity of level II studies.

The Watch_PAT system offers several potential advantages over other portable monitoring systems. First, the Watch_PAT detects respiratory events during epochs of sleep estimated by automated analysis of actigraphy and calculates an RDI based on this sleep time. Most ambulatory devices calculate an RDI based on the recording time, since they cannot differentiate wake from sleep. This method may lead to reduced sensitivity and artificially increased specificity. Second, the Watch_PAT can detect respiratory events that meet the Chicago criteria for scoring a hypopnea but do not cause a substantial desaturation. Since the Watch_PAT can detect sympathetic activation associated with arousal from sleep, these events are included in the PAT RDI. In addition, the Watch_PAT calculates an ODI based on desaturations of 4% or greater, a measure that is less inclusive in the detection of obstructive respiratory events but compares very well to the Medicare criteria for scoring events. Third, the Watch_PAT was simple to use for participants in our study, with a low failure rate for single use (no technical failures for the home studies). Fourth, performing Watch_PAT studies requires minimal effort from staff. Subject instruction for operating the device only required 5 to 10 minutes in our study, and the analysis of the studies was fully automated. Uploading a study from the COMPACTFLASH disk to the computer combined with automated analysis required less than 3 minutes (Dell Optiplex 1.8 GHz GX240 Pentium 4).

There are several potential disadvantages to the Watch_PAT system as well. The principal one relates to the novelty of the PAT signal and the lack of conventional measures of airflow, chest/abdominal movement, and body position on the studies. Thus, apneas that meet Medicare criteria but do not yield at least a 4% desaturation will not be included in the PAT ODI. This was the source of the disagreement between the LAB-PAT ODI and PSG RDLM in subject #3 in our study (see Figure 3). Also, the Watch_PAT system reports a PAT RDI that does not differentiate

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the type of respiratory event (e.g., obstructive apnea, mixed apnea, central apnea, hypopnea) and cannot calculate a supine-only RDI, since body position is not detected by the device. These limitations may prove unsatisfactory in determining a differential diagnosis in some patients. Furthermore, using our clinical approach to assess agreement, concordance was not achieved in 28% of the cases when the HOME-PAT RDI was compared to the PSG RDI. Finally, the PAT signal is also susceptible to artifact due to certain arrhythmias such as atrial fibrillation and premature atrial contractions, and its response may be limited by certain medications (e.g., α-adrenergic receptor-blocking agents and nitrates).

There are a number of limitations to our study. The study included a small number of consenting patients with suspected OSA at only 1 sleep center. Thus, the prevalence of OSA and mean RDI in our study population were high. We therefore cannot assess whether these results would extend to populations with a lower probability of OSA, for example patients at primary care facilities. One important use of a home diagnostic device might be to exclude OSA in a population where the pretest probability is relatively low, thus saving the cost of in-laboratory PSGs. A study investigating the accuracy of home studies with the Watch_PAT device in such a population would be worthwhile. Another limitation of our study is that we evaluated the accuracy of the Watch_PAT device in the home by comparing measurements in that environment on one night to the gold standard PSG acquired in the laboratory on a different night. There are inherent flaws with this method as mentioned above and in previous publications. We also did not perform event-by-event analysis of the Watch_PAT and PSG data to determine agreement due to technical limitations of synchronizing PSG and Watch_PAT data while maintaining blinded manual scoring of the PSG.

In conclusion, this study indicates that the Watch_PAT device is easy to use for home sleep studies with a low failure rate for single use and minimal technician time when compared with PSG. Based on the likelihood ratios for our home study results, the system yielded a very large increase in the probability of having moderate to severe OSA (Chicago criteria) for a PAT RDI ≥ 12.5 events per hour (abnormal cases: PSG RDL C ≥ 15 events per hour) and a large reduction in the probability of having moderate to severe OSA for a PAT RDI < 12.5 events per hour. Thus, the Watch_PAT could become a useful diagnostic tool in diagnosing moderate to severe OSA in high-risk populations where the prevalence of sleep-disordered breathing is high. Studies in other sleep disorder centers are needed to confirm our experience. Nonetheless, the Watch_PAT system could become an important clinical tool and may play an important role in reducing per patient cost in diagnosing and managing OSA.

REFERENCES


33. Hanley JA, Mcneil BJ. The meaning and use of the area under a receiver operating characteristic (ROC) curve. Radiology 1982;143:29-36.


