Evaluation of a Portable Device Based on Peripheral Arterial Tone for Unattended Home Sleep Studies*

Amir Bar, MD; Giora Pillar, MD, DSc; Itsik Dvir, DSc; Jacob Sheffy, PhD; Robert P. Schnall, DSc; and Peretz Lavie, PhD

Background: **Diagnosis of obstructive sleep apnea syndrome (OSAS) by ambulatory systems is a growing practice in view of the large number of patients awaiting correct diagnosis. The Watch PAT100 (WP100) [Itamar Medical; Caesarea, Israel] is a portable device based on the peripheral arterial tone (PAT) signal, and is designed for unattended home sleep studies.**

Objectives: **To evaluate the efficacy, reliability, and reproducibility of the WP100 device for the diagnosis of OSAS as compared to in-laboratory, standard polysomnographic-based manual scoring.**

Design and methods: **One hundred two subjects (78 men; 69 patients with OSAS and 33 normal volunteers; mean ± SD age, 41.4 ± 15.2 years; body mass index, 26.8 ± 5.5) underwent in-laboratory full polysomnography simultaneously with WP100 recording. Fourteen subjects also underwent two additional unattended home sleep studies with the WP100 alone. The polysomnography recordings were blindly scored for apnea/hypopnea according to the American Academy of Sleep Medicine criteria (1999), and the polysomnography respiratory disturbance index (RDI) [PSG-RDI] was calculated. The WP100 data were analyzed automatically for the PAT RDI (PRDI) by a proprietary algorithm that was previously developed on an independent group of subjects.**

Results: **Across a wide range of RDI levels, the PRDI was highly correlated with the PSG-RDI ($r = 0.88$, $p < 0.0001$), with an area under the receiver operating characteristic curve of 0.82 and 0.87 for thresholds of 10 events per hour and 20 events per hour, respectively. The PRDI scores were also highly reproducible, showing high correlation between home and in-laboratory sleep studies ($r = 0.89$, $p < 0.001$).**

Conclusion: **The WP100 may offer an accurate, robust, and reliable ambulatory method for the detection of OSAS, with minimal patient discomfort.** ***(CHEST 2003; 123:695–703)***

Key words: ambulatory; automatic analysis; obstructive sleep apnea syndrome; peripheral arterial tone; respiratory disturbance index; sleep

Abbreviations: ASDA = American Sleep Disorders Association; AUC = area under the curve; BMI = body mass index; ESS = Epworth sleepiness scale; OSAS = obstructive sleep apnea syndrome; PAT = peripheral arterial tone; PRDI = peripheral arterial tone respiratory disturbance index; PSG-RDI = polysomnography respiratory disturbance index; RDI = respiratory disturbance index; ROC = receiver operating characteristic; WP100 = Watch PAT100

Obstructive sleep apnea syndrome (OSAS) is considered to be a major public health problem. The prevalence of OSAS is estimated at 2% and 4% for adult women and men, respectively, most of whom are undiagnosed and untreated.[1] The in-laboratory sleep study using full polysomnography and the manual scoring criteria set by the American Academy of Sleep Medicine is considered the "gold standard" for OSAS diagnosis.[2] The severity of the disorder is expressed as the respiratory disturbance index (RDI), which is the number of apneas/hypopnea events per hour of sleep. The high cost of in-laboratory, full-night polysomnography, together with long waiting lists for sleep studies, have led to the commonly used procedure of "split-night" for

---

*From Itamar Medical Ltd. (Drs. Bar, Dvir, Sheffy, and Schnall), Caesarea; and Sleep Laboratory (Drs. Pillar and Lavie), Bruce Rappaport Faculty of Medicine, Technion, Israel Institute of Technology, Haifa, Israel.

Drs. Bar, Dvir, Sheffy, and Schnall are employees of Itamar Medical Ltd. Dr. Pillar and Professor Lavie are consultants in that firm.

Supported in part by a grant from Itamar Medical Ltd., Caesarea, Israel.

Manuscript received December 28, 2001; revision accepted September 25, 2002.

Correspondence to: Peretz Lavie, PhD, Sleep Laboratory, Gutwirth Bldg, Technion City, Haifa 32000, Israel; e-mail: plavie@tx.technion.ac.il

patients with OSAS, as well as to the development of a variety of ambulatory sleep study systems.[3]

The earliest ambulatory devices were based on overnight pulse oximetry alone, an easy and simple technology for diagnosing OSAS.[4] However, it has been shown that the pulse oximeter suffers from limited accuracy.[5,6] Portable full polysomnography and other multiple-channel ambulatory devices are frequently complex and cumbersome.[7]

The American Sleep Disorders Association (ASDA) has classified sleep study systems into four categories: level 1, in-laboratory attended standard polysomnography; level 2, unattended home sleep study with comprehensive portable devices incorporating the same channels as the in-laboratory standard polysomnography; level 3, unattended devices, which measure at least four cardiorespiratory parameters; level 4, unattended devices recording one or two parameters.[8]

The Watch PAT100 (WP100) [Itamar Medical; Caesarea, Israel] is a four-channel unattended ambulatory device (level 3) based on the peripheral arterial tone (PAT) signal with three additional channels: heart rate (derived from the PAT signal), pulse oximetry, and actigraphy (both are embedded in the device). The PAT signal measures the arterial pulsatile volume changes of the finger that are regulated by the α-adrenergic innervation of the smooth muscles of the vasculature of the finger, and thus reflects sympathetic nervous system activity.[9] The WP100 indirectly detects apnea/hypopnea events by identifying surges of sympathetic activation associated with the termination of these events. This information is further combined with heart rate and pulse oximetry data that are analyzed by the automatic algorithm of the system (which was developed on a prior group of patients). This detects respiratory events and calculates the PAT RDI (PRDI).

The primary objective of this study was to evaluate the efficacy of the device for diagnosing OSAS, by comparing its results to simultaneous polysomnography recordings. Secondary objectives were to evaluate the feasibility and reproducibility of the WP100 in an unattended home setting.

Materials and Methods

Study Population

The study group consisted of 69 consecutive subjects referred to the clinical sleep laboratory of the Technion Sleep Medicine Center (Haifa, Israel) with suspected OSAS, and 33 additional healthy adult volunteers, without complaints of snoring or daytime sleepiness. None of the subjects had previously undergone a polysomnographic study. Seventy-eight subjects were men, and 24 were women. The mean ± SD age of the group was 41.4 ± 15.2 years. The men were slightly more obese (body mass index [BMI] of 27.5 ± 5.5 vs 24.5 ± 4.8) and had higher Epworth sleepiness scale [ESS] scores (8.7 ± 5.8 vs 7.0 ± 5.7, respectively) [Table 1]. Twenty percent of the subjects had hypertension, and 4% had coronary artery disease. The exclusion criteria for the study were as follows: permanent pacemaker, nonsinus cardiac arrhythmias, peripheral vasculopathy or neuropathy, severe lung disease, status postbilateral cervical or thoracic sympathectomy, finger deformity that precludes adequate sensor application, use of α-adrenergic receptor blockers (24-h washout period required), and alcohol or drug abuse during the last 3 years. The study protocol was approved by the Ethics Committee of the Rambam Medical Center, and the subjects gave their written informed consent prior to participation.

Study Procedure

The study was a blinded study comparing the automatically scored WP100 results (PRDI) to the manually scored polysomnography RDI (PSG-RDI). The WP100 and polysomnography data were recorded simultaneously in a time-synchronization manner in the sleep laboratory. A subgroup of 14 patients from the study cohort also underwent two additional unattended home sleep studies with the WP100 device only. The subjects were selected for this subgroup based on their home location, and only included those subjects within a 30-mile range of the sleep laboratory. In the WP100 home studies, the device was delivered to the patient's home, the patient applied the device, and following the overnight recording the device was returned to the sleep center for automatic analysis. The requirements for WP100 data analysis are a personal computer and the proprietary PAT software, which can be run on Windows 98 operating system (Microsoft; Redmond, WA) or higher.

The overnight sleep studies were considered acceptable for data analysis if none of the following rejection criteria occurred: (1) polysomnography-related rejection (polysomnography actual sleep time < 1.5 h, technical failure of synchronizing the polysomnography to the WP100, and poor quality of polysomnographic recording); and (2) WP100-related rejection (WP100 valid sleep time < 1.5 h). Patient demographic and medical information, as well as the ESS questionnaire, were acquired by interview prior to the sleep study.

Equipment

WP100 Device: The WP100 used in the unattended sleep studies is comprised of a battery-powered, forearm-mounted console unit placed just above the wrist, and two finger-mounted probes: pulse oximetry and PAT probe (Fig 1).

Forearm-Mounted Console Unit: This unit provides the power supply, first-level signal processing, signal conditioning and filtering, data acquisition, and storage functions required for monitoring the pulse oximetry and PAT signals. In addition, data from an embedded actigraph and heart rate derived from the PAT

Table 1—*Study Group Mean Age, BMI, and Total ESS Score by Gender**

Variables	Male (n = 78)	Female (n = 24)	Overall (n = 102)
Age, yr	42.0 ± 15.0	39.6 ± 16.2	41.4 ± 15.2
BMI	27.5 ± 5.5	24.5 ± 4.8	26.8 ± 5.5
ESS score	8.7 ± 5.8	7.0 ± 5.7	98.3 ± 5.8

*Data are presented as mean ± SD.

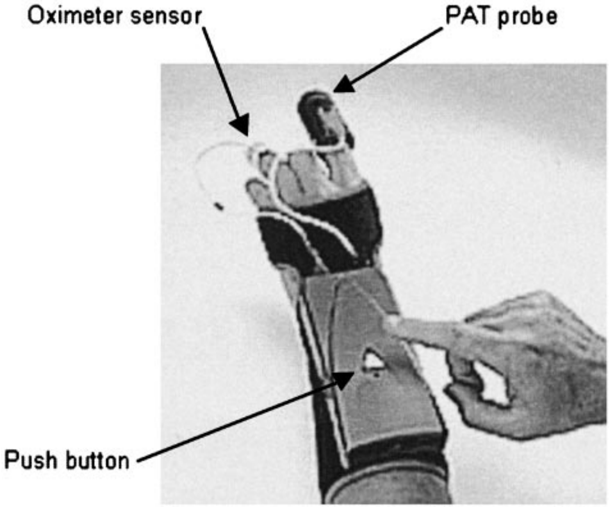

FIGURE 1. The WP100 device worn on a forearm. The PAT sensor and the built-in pulse oximetry sensor are attached to the fingers. The acquired PAT and pulse oximeter data, as well as the embedded actigraph data, are stored on a compact flash disk (not shown). The device is switched on by the indicated push button.

signal are continuously recorded. All four signals are recorded at a sample rate of 100 Hz and stored on a removable flash disk throughout the study.

Pulse Oximeter Probe: A standard-type pulse oximeter probe (Nonin OEM 2 oximetry module, 8000J; Nonin; Ellös, Sweden) is applied to a finger in a conventional manner according to the instructions of the manufacturer.

PAT Probe: The second finger probe measures the PAT of the patient's fingertip. Previous applications of this technology have been described[9–12]; however, in this study the method was specifically adapted for ambulatory unattended use.

Essentially, the WP100 finger sensor applies a uniform pressure field over the distal two thirds of the finger, including the fingertip. Previous plethysmographic devices that enveloped the fingertip, such as venous occlusion plethysmography collection cuffs, tended to be pushed off the finger when pressurized. However the split-thimble design of the PAT probe allows it to actively clamp itself to the finger while applying a pressure field that facilitates the unloading of arterial wall tension without causing distal venous pooling and distension, thus avoiding the induction of venoarterial-mediated vasoconstriction.[13]

A transmission mode photoelectric plethysmograph situated at opposing lateral sides at about the middle of the distal phalanx is used to measure the optical density changes associated with pulsatile blood volume changes of the finger. The proximal two thirds of the pressure field buffers the sensing region from extraneous and artifactual signals such as perturbations in the venous system.

Isobaric, Volume-Displacement PAT Probe Design: A unique feature of the PAT finger probe is its ability to generate its own pressure field at a fixed level of pressure irrespective of the size of the finger.[14] The pressure field is created by the insertion of a finger into the probe (Fig 2, *top*, *A*). When the finger is inserted into the probe, a proportionate amount of air is shifted from the inner compartment of the probe to its outer compartment, causing the pretensioned outer membrane to be pushed off the wall of the inner shell and thus apply pressure to the air within the probe. The elastic properties of the balloon-like outer membrane are such that over a wide range of volumes it creates a constant pressure.

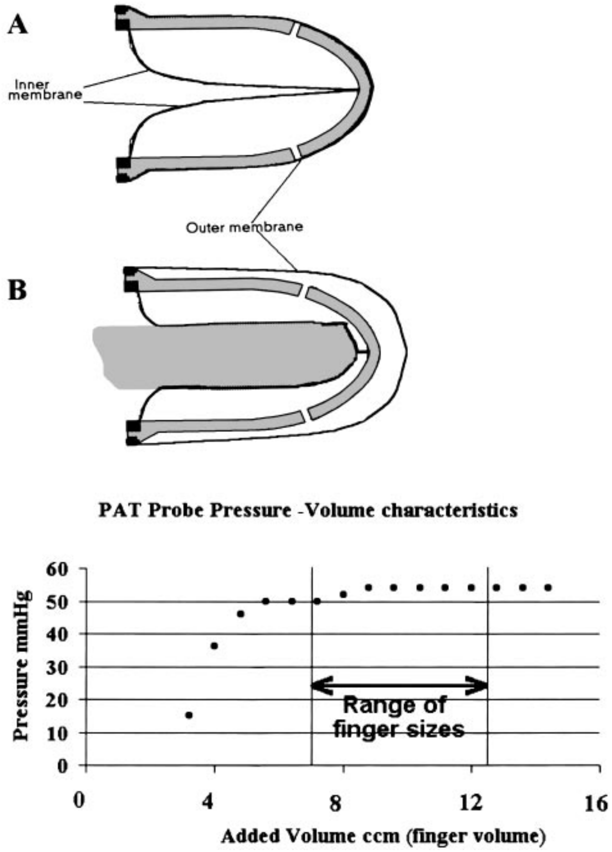

FIGURE 2: *Top*, *A*: The WP100 probe contains an inner and an outer membrane on either side of a rigid plastic thimble. Before insertion of the finger, approximately 10 mL of air is situated between the inner membrane and the plastic thimble. Since the inner membrane is not stretched, the air is at atmospheric pressure. The outer membrane is fitted to the external wall of the plastic thimble, and is slightly stretched from its natural size. *Top*, *B*: When the finger is inserted into the probe, a proportionate amount of air is shifted from the inner compartment of the probe to its outer compartment, causing the pretensioned outer membrane to be pushed off the wall of the inner shell and to thus apply pressure to the air within the probe. Insertion tabs for aiding in the insertion of the finger and an external probe cover are not shown. *Bottom*: pressure vs added finger volume graph of the PAT finger probe. It can be seen that beyond an added value of approximately 7 mL, the applied pressure remains constant. This constant pressure at variable volume behavior is characteristic of elastic balloons.

The actual pressure that the probe generates in response to differing volume displacements is shown in Figure 2, *bottom*, *B*. This shows that the probe applies a common and constant level of pressure over a broad range of finger sizes encountered in an adult population.

The physical basis for the ability of the probe to generate a fixed pressure is described by the law of Laplace, which relates the pressure within a distensible hollow object to the wall tension and the radius such that the pressure is proportional to wall tension divided by radius. In the case of elastic balloons in general, and in the specific case of the elastic outer membrane of the probe, wall tension varies in direct proportion to radius, and thus pressure remains constant over a large range of volumes.

Automatic Algorithm: The automatic algorithm of the WP100 is based on the PAT signal amplitude, heart rate, and oxygen saturation. The sleep/wake detection is based on data recorded by the built-in actigraph.

Polysomnography

Data Collection: Standard in-laboratory, overnight polysomnography was performed using a computerized polysomnography system (Embla; Flaga Medical; Reykjavik, Iceland), with the following channels: EEG (C3-A2 and O2-A1), electrooculogram (right and left), chin electromyogram, arterial oxygen saturation, nasal-oral airflow (thermistor), ECG, chest and abdominal wall motion (piezo electrodes), bilateral tibialis electromyogram, body position, and auxiliary channel with a synchronizing signal from the WP100 device.

Scoring: The polysomnography recordings were scored manually for sleep stages[15] and respiratory events (apnea/hypopnea) according to the American Academy of Sleep Medicine criteria, 1999.[2] An apnea/hypopnea event was defined as an airflow amplitude reduction of > 50% from the baseline lasting at least 10 s, or having a less significant reduction in the airflow amplitude, but with the presence of arousal or oxygen desaturation of at least 3%. The PSG-RDI was calculated as the number of apnea/hypopnea events per hour of sleep. The scorer had no access to the WP100 data or results while scoring the polysomnography data.

Statistical Analysis

The correlation between the PRDI and PSG-RDI was assessed using the Pearson correlation coefficient and Bland-Altman plots. Receiver operating characteristic (ROC) analysis was carried out to evaluate the WP100 diagnostic capability. A threshold of PSG-RDI > 10 was used as the cut-off point for OSAS diagnosis,[16] and PSG-RDI > 20 was defined as the commonly used cut-off point for intended CPAP treatment.[17] Based on these threshold definitions, ROC curves were derived, and areas under the curves (AUCs) were calculated.

RESULTS

Of 102 in-laboratory studies, 3 studies were rejected: 2 polysomnography studies had synchronization failure and 1 study was rejected due to PAT valid sleep time < 1.5 h. Three of the 28 at-home PAT studies were originally rejected due to technical failure but were repeated successfully; thus, the at-home rejection rate was 3 of 31 studies. None of the participants requested to withdraw from the study due to discomfort or any other reason, and no adverse or side effects were reported. A wide range of OSAS severities were represented in the study group, with about equal number of subjects[16–19] in each of the following RDI categories: 0 to 10, 11 to 30, 31 to 50, and > 50 events per hour.

Figure 3 shows a scatter graph that demonstrates the high and statistically significant correlation coefficient between the PSG-RDI scores and the PRDI scores ($r = 0.88$, $p < 0.0001$, $n = 99$). Figure 4 shows a Bland-Altman plot of the differences between the PSG-RDI and the PRDI values vs the

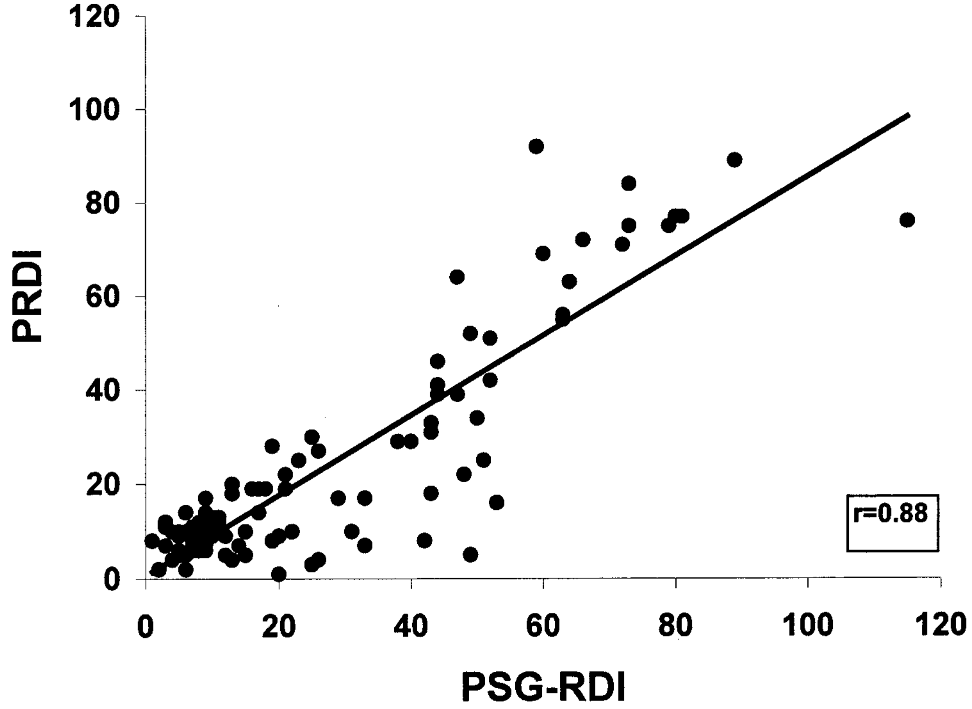

FIGURE 3. Scatter plot of PRDI (x axis) vs standard PSG-RDI (y axis). A very high and statistically significant correlation ($r = 0.88$, $p < 0.0001$, $n = 99$) was found between the PRDI (by automatic algorithm) and the PSG-RDI (manual scoring).

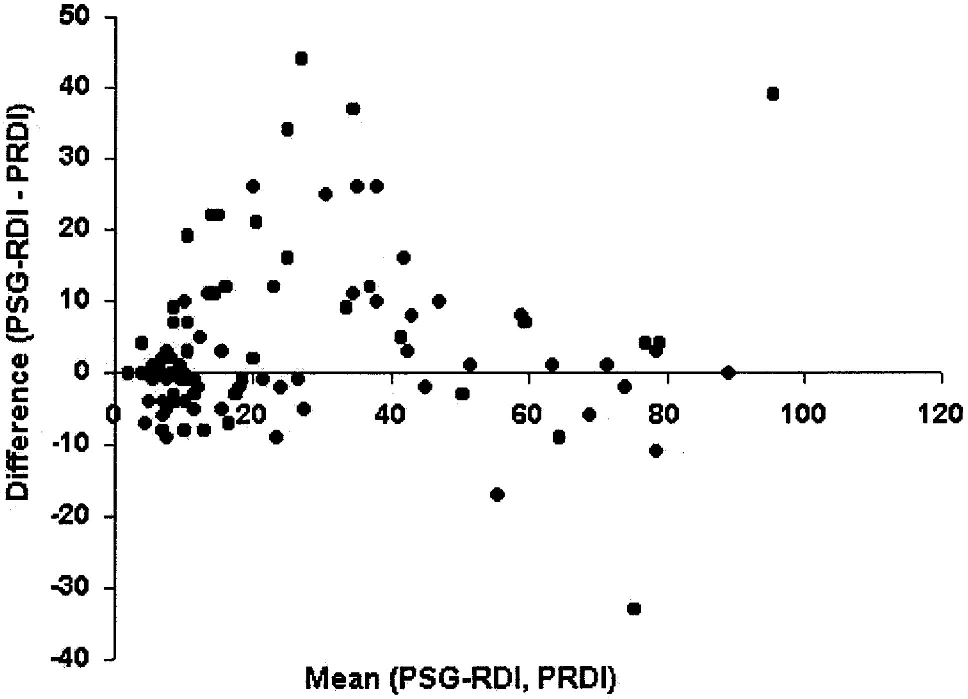

FIGURE 4. Bland-Altman plot (n = 99), showing differences between PSG-RDI and PRDI (y axis) vs the corresponding average values of the two values (x axis). Across a wide range of OSAS severities (RDI levels), there was a good agreement between PRDI and the PSG-RDI.

corresponding averages of the two RDI indexes. There was a slight tendency for the PAT to underscore events in the mild range of OSAS, and to overscore events in the severe range.

As can be seen in Figures 5, 6, the WP100 results in the sleep laboratory studies were highly reproducible in the home sleep studies ($r = 0.89$, $p < 0.001$, n = 14), with high correlation coefficient between the two home sleep studies ($r = 0.94$, $p < 0.001$, n = 14), indicating high internight consistency.

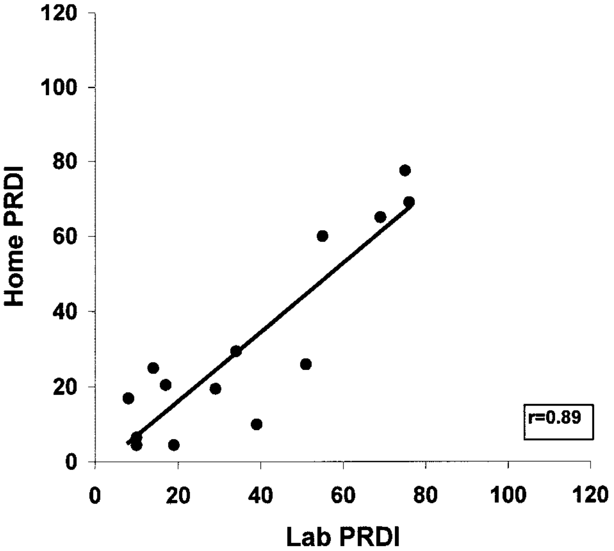

FIGURE 5. Scatter plot of home PRDI: mean of two nights (y axis) vs PRDI recorded in the sleep laboratory (Lab) [x axis]. A highly significant correlation ($r = 0.89$, $p < 0.001$, n = 14) was found.

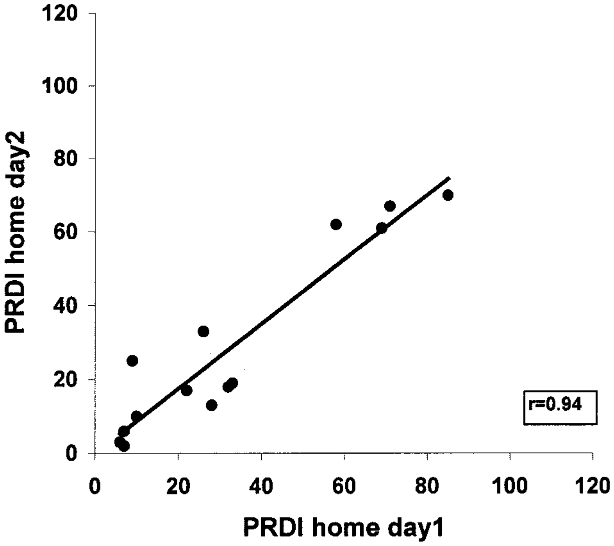

FIGURE 6. Scatter plot of repeated home PRDI values. PRDI of the second home sleep study (y axis) is plotted against PRDI recorded in the first home sleep study (x axis). A highly significant correlation ($r = 0.94$, $p < 0.001$, n = 14) was found between the two at-home sleep studies.

Figure 7 shows the ROC curve reflecting the diagnostic capability of PRDI when the threshold of PSG-RDI was set at 10 for OSAS diagnosis.[16] Figure 8 shows the ROC curve reflecting the diagnostic capability of PRDI when the threshold of PSG-RDI was set at a value of 20, which represents a PSG-RDI level at which continuous positive airway pressure therapy is indicated.[17] The areas under the ROC curves were 0.82 ($p < 0.0001$) for the diagnostic threshold (PSG-RDI > 10), and 0.87 ($p < 0.0001$) for the therapeutic threshold (PSG-RDI > 20).

Discussion

This study shows that the WP100 is a simple, reliable and accurate device for ambulatory diagnosis of OSAS. The in-laboratory measured PRDI results were well correlated with the in-laboratory PSG-RDI results ($r = 0.88$, $p < 0.0001$), with good efficacy for both OSAS diagnosis (RDI > 10)[16] and for CPAP therapy indication (RDI > 20)[17] [AUC of 0.82 and 0.87, respectively]. The in-laboratory PRDI results were highly reproducible in the home sleep studies, with correlation coefficients of 0.89 and 0.94, for laboratory vs home and between two home sleep studies, respectively. Given the expected internight variability for RDI,[18,19] the high consistency found in this study is even more significant. The device reliability is also demonstrated by the relatively low rejection rates; 1 of 102 studies in the sleep laboratory, and 10% of the home sleep studies, which were carried out as unattended self-administered studies. For comparison, data loss rate was evaluated as 4 to 33% with other unattended home sleep systems.[7,20–23]

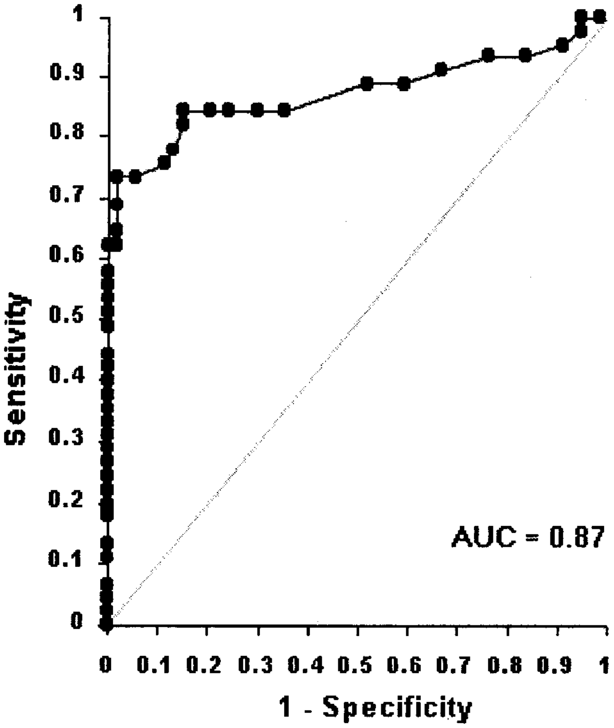

FIGURE 8. ROC curve for PRDI when the cutoff threshold was defined as PSG-RDI > 20. AUC for the curve is 0.87 ($p = 0.0001$), showing the potentially high sensitivity and specificity in diagnosing OSAS of a severity requiring treatment.

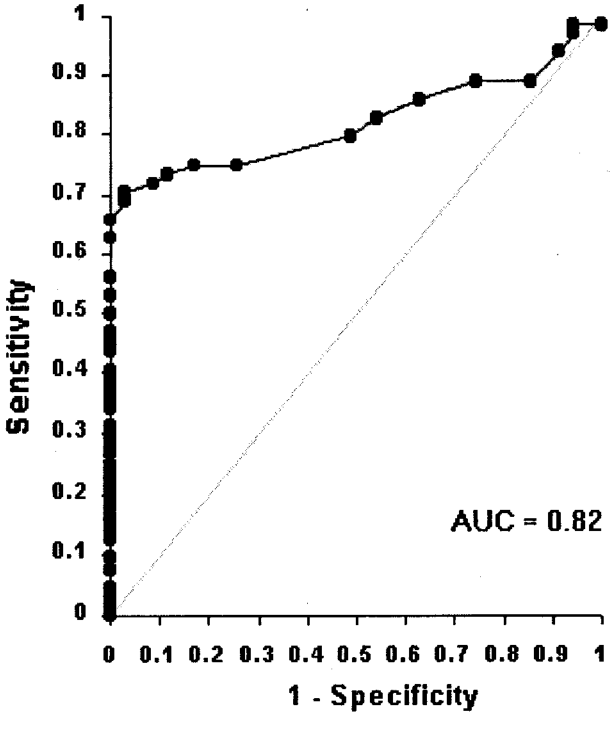

FIGURE 7. ROC curve for PRDI when the cutoff threshold was defined as PSG-RDI > 10. AUC for the curve is 0.82 ($p = 0.0001$), showing the potentially high sensitivity and specificity in diagnosing OSAS.

Over 80% of patients with moderate-to-severe OSAS are undiagnosed and untreated, which can subsequently lead to the severe sequelae of the syndrome. Kapur et al[24] concluded that patients with undiagnosed OSAS had considerably higher medical costs than age and sex-matched non-OSAS subjects, and that the OSAS severity was associated with the magnitude of medical costs. The long waiting lists for in-laboratory polysomnography studies, which are expensive and time consuming, have led to an intensive search for ambulatory alternatives. According to the ASDA standards of practice (1994), sleep study devices are classified into four levels, from the attended, in-laboratory, full polysomnography (level 1) to the unattended, at-home, single/double-channel recording (ASDA level 4).[8] In general, there appears to have been a tradeoff between the amount of information and the simplicity of the device. Simple devices tend to have a high level of feasibility and saving of time and expenses, but provide less information. For example, Portier et al[7] evaluated unattended, at-home polysomnography studies (ASDA level 2) vs in-laboratory polysomnography studies, using the same recorded channels. They found that the reliability of the studies was associated with the quality of data obtained under the unattended conditions, where 33% of the recordings were not adequate for data analysis, and a further 11% of the studies had discordant results. The rejection rate of the WP100 device (10%) is in the lower-to-middle range of the ASDA grade level III devices, which were estimated to have rejection rates in the range of 4 to 24%.[20–24] Other ambulatory devices from this category could also demonstrate relative simplicity and low rejection rate, but showed unsatisfactory accuracy. Esnaola et al[25] studied 150 individuals with suspected OSAS, who underwent full polysomnography simultaneously with level III devices and reported AUC values from 0.67 to 0.76. Cirignotta et al[26] reported that the automatic scoring of such a device was unreliable in assessing patients with complicated OSAS. In contrast to these reported devices, the WP100 appears to have both the advantage of simplicity (recording only from two finger probes) and high accuracy.

The device is based on the PAT signal, a measurement of the pulsatile volume changes in the vascular bed at the fingertip, providing continuous monitoring of the pulse rate and detecting digital vasoconstriction events, both of which are affected by the sympathetic nervous system. Grote et al[9] has shown that the control of the finger arteries is almost exclusively mediated by α sympathetic receptors, so that PAT-detected episodes of vasoconstriction actually reflect sympathetic activation. Pitson and Stradling[27] reported that repeated occurrence of sleep apnea and hypopnea events causes arterial oxygen desaturation, as well as arousal from sleep with periodic episodes of increased sympathetic nervous system activation. These authors used heart rate change and the pulse transit time as indices of sympathetic activation and found that these were less well correlated with the apnea/hypopnea index ($r = 0.51$ and 0.65, respectively).

The PAT technology is a unique and relatively new concept of noninvasive measurement of sympathetic activation levels that appears to be very accurate for detecting sleep-disordered breathing events. The self-contained pressurizing mechanism of the probe allows it to be lightweight and silent, essential for a practical ambulatory device. Its ability to reliably apply a predetermined and constant level of pressure over a broad range of finger sizes is essential for the accuracy, robustness, and reproducibility of the method, and was also vital for the development of the algorithm.

The first study that demonstrated the PAT signal diagnostic capability for patients with OSAS was performed using a bedside version of the PAT system, which was automatically analyzed using PAT signal attenuation and pulse rate criteria alone. In that study, Schnall et al[10] found a high correlation between standard polysomnography scoring of total apnea-hypopnea events and PAT-vasoconstriction events with concurrent tachycardia. Later, Pillar et al[11] showed that detection of apnea and hypopnea events based on combined data from PAT and pulse oximetry was highly correlated with standard polysomnography scored results, a finding that was confirmed by Pittman et al[12] utilizing both manual and automatic analysis. O'Donnell et al[28] further explored the PAT response in patients with OSAS. They experimentally induced upper airway obstruction and have shown that airflow obstruction in patients with OSAS leads to a PAT signal attenuation in a "dose-response" manner, *ie*, greater airflow obstruction causes greater PAT attenuation.

The criteria of the automatic algorithm for respiratory disturbance event in the present study were set as either a substantial digital vasoconstriction ($> 50\%$) or substantial arterial oxygen desaturation ($> 4\%$), or a milder degree of vasoconstriction ($> 30\%$) with concurrent pulse rate acceleration ($> 10\%$) or subthreshold arterial oxygen desaturation ($> 3\%$). Based on the actigraphic data, periods of sleep and wakefulness were identified, and the automatic algorithm RDI was calculated per hour of detected sleep. Although actigraphically determined sleep time is not as accurate as polysomnography, this feature is an improvement over other modified portable devices, which provide RDI values per total recording time rather than per the actual sleep time, which may lead to a biased RDI.

It should be noted that the population we studied did not include patients with central sleep apnea. We therefore assume that, at this stage, the current algorithm would not differentiate between obstructive and central apneas. However, given the very low prevalence of central apnea among the referred population to diagnostic sleep laboratories and the fact that the treatment of choice is usually the same, we do not consider this to be a major disadvantage. It should be also noted that sympathetic activation during sleep is not exclusively associated with the resumption of respiration after disordered breathing events, but may also arise in association with a variety of other conditions that may cause sleep arousals such as gross body movements, periodic leg movements, or changes in upper airway resistance. As outlined before, in order to maximize the specificity of the WP100 automatic algorithm to detect respiratory disturbance events, it was designed to be based not only on the presence of vasoconstriction episodes but it also takes into account their periodic nature, typical length, and combination with heart rate and oxygen desaturation changes. All these parameters were tuned in an optimizing process over a prior training set of results and were shown to give robust correlation with the polysomnography results in the validation set of the present study. Recently, we built a separate algorithm which utilizes the PAT signal to detect ASDA-defined arousals during sleep regardless of their source. This latter algorithm was based on a combination of two features of the PAT signal, amplitude attenuation and pulse rate increase. Validating the algorithm on a group of 96 patients that included normal subjects, patients with sleep apnea, and patients with periodic leg movements during sleep revealed a high correlation of 0.88 between manually scored ASDA-defined arousals and the automatically derived PAT autonomic arousal index. We believe that utilizing a combination of the features of the above-described algorithms to analyze a PAT record will allow us to distinguish between sympathetic activation due to respiratory events or due to other causes. Thus, in cases where the result of an RDI selective algorithm is consistent with or higher than that of the autonomic arousal algorithm, it can be reliably used to provide sleep apnea diagnosis. In cases where the PAT reveals a high arousal index but a low RDI, additional disorders such as periodic limb movements or upper airway resistance syndrome should be suspected and further explored. It is yet to be determined, however, if specific features of the digital response may be further analyzed to provide additional useful information about the underlying cause of the sympathetic activation.

A relatively high consistency was found between PRDI in the laboratory and at home, as well as between at-home studies, compared to previous studies that reported rather large night-to-night variability of RDI.[19,21] It is possible that the consistency found in this study results from the relatively high incidence of patients with severe apnea re-studied at home. We conclude from these results that the WP100 showed a high level of reproducibility, although this may have been related to the specific population studied.

The ability of the PAT system to detect sleep-related respiratory disturbances could be affected by peripheral vasculopathy or neuropathy, and/or autonomic nervous system dysfunction, through the disruption of the normal response of the peripheral arteries to sympathetic activations. Nevertheless, the presence of such conditions should only be applied as exclusion criteria in extremely severe cases but not for example in the common diabetic patient. Obviously, patients who are treated with α-blocker medications, those who underwent bilateral sympathectomy, and others with Raynaud disease or acrocyanosis are not candidates for the WP100 device. In patients with severe finger deformity (*eg*, rheumatoid arthritis), the adequate applying of the PAT probe could be a technical problem. In fact, none of the subjects in the current study were excluded on the basis of these conditions, and only two subjects were excluded because of treatment with α-blocking agents. Therefore, the use of the device was not in practice limited by these pathologies, and the vast majority of the subjects with suspected OSAS would be eligible to use the WP100 device.

This study has several potential limitations. First, the study population consisted of patients with snoring/sleep apnea syndrome and healthy volunteers. One could argue that the accuracy of PAT in recognizing respiratory disturbances might be different in other patient populations (such as insomniacs). However, some of our patients complained of difficulties falling and maintaining sleep along with the hypersomnolence, and we did not notice a decreased accuracy of the WP100 in recognizing events in these individuals. Nevertheless, expanding this study to other patient populations will add more information regarding its applicability. In addition, we have evaluated the PAT for apneas and hypopneas but not for increased upper airway resistance syndrome. Respiratory effort related arousals are well recognized, and indeed it would be reasonable to be able to recognize them with this device, as these are also associated with sympathetic activation. However, this was beyond the scope of this study and is currently being investigated in a separate study.

CONCLUSION

Despite these limitations, we believe that this study shows that the WP100 is a simple, reliable, and accurate device for diagnosing OSAS in the unattended home set-up. Using a device with sensors placed only on the fingers and forearm makes it simple to self-administer and well tolerated. Using the automated scoring algorithm allows for objectivity and is time saving.

REFERENCES

1 Young T, Evans L, Finn L, et al. Estimation of the clinically diagnosed proportion of sleep apnea syndrome in middle aged men and women. Sleep 1997; 9:705–706

2 American Academy of Sleep Medicine. Sleep-related breath-

ing disorders in adults: recommendations for syndrome definition and measurements techniques in clinical research; the report of an American Academy of Sleep Medicine Task Force. Sleep 1999; 22:667–689

3 Yamashiro Y, Kryger MH. CPAP titration for sleep apnea using a split-night protocol. Chest 1995; 107:62–66

4 Decker MJ, Hoekje PL, Strohl KP. Ambulatory monitoring of arterial oxygen saturation. Chest 1989; 95:717–22

5 Levy P, Pepin JL, Deschaux Blanc C, et al. Accuracy of oximetry for detection of respiratory disturbances in sleep apnea syndrome. Chest 1996; 109:395–399

6 Epstein LJ, Dorlac GR. Cost-effectiveness analysis of nocturnal oximetry as a method of screening for sleep apnea-hypopnea syndrome. Chest 1998; 113:97–103

7 Portier F, Portmann A, Czernichow P, et al. Evaluation of home versus laboratory polysomnography in the diagnosis of sleep apnea syndrome. Am J Respir Crit Care Med 2000; 162:814–818

8 ASDA Standards of Practice Committee. Portable recording in the assessment of obstructive sleep apnea. Sleep 1994; 17:378–392

9 Grote LB, Hedner J, Ding Z. Alteration of digital pulse amplitude reflects α adreno-receptor mediated constriction of the digital vascular bed [abstract]. Sleep 2001; 24(Suppl): 133R

10 Schnall RP, Shlitner A, Sheffy J, et al. Periodic, profound peripheral vasoconstriction: a new marker of obstructive sleep apnea. Sleep 1999; 22:939–946

11 Pillar G, Malhotra A, Fogel R, et al. Detection of obstructive sleep disordered breathing events utilizing peripheral arterial tonometry and oximetry [abstract]. Sleep 2000; 23(Suppl): 304K1

12 Pittman S, Tal N, Pillar G, et al. Automatic detection of obstructive sleep-disordered breathing events using peripheral arterial tonometry and oximetry [abstract]. J Sleep Res 2000; 9(Suppl):309

13 Henriksen O, Sejrsen P. Local reflex in microcirculation in human cutaneous tissue. Acta Physiol Scand 1976; 98:227–231

14 Schnall RP. Pressure applicator devices particularly useful for non-invasive detection of medical conditions. Geneva, Switzerland: World Intellectual Property Organization (WIPO), Published International Application WO 99/63884.16, December 1999

15 Rechtschaffen A, Kales A, eds. A manual of standardized terminology, techniques and scoring system for sleep stages of human subjects. Los Angeles, CA: BIS/BRI, UCLA, 1968

16 Partinen M, Hublin C. Epidemiology of sleep disorders. In: Kryger MH, Roth T, Dement WC III, eds. Principles and practice of sleep medicine. Philadelphia, PA: W.B. Saunders, 2000; 558–579

17 Sanders MH. Medical therapy for obstructive sleep apnea-hypopnea syndrome. In: Kryger MH, Roth T, Dement WC III, eds. Principles and practice of sleep medicine. Philadelphia, PA: W.B. Saunders, 2000; 879–893

18 Chediak AD, Acevedo-Crespo JC, Seiden DJ, et al. Sleep disordered breathing: nightly variability in the indices of sleep-disordered breathing in men being evaluated for impotence with consecutive night polysomnograms. Sleep 1996; 19:589–593

19 Le Bon O, Hoffmann G, Tecco J, et al. Mild to moderate sleep respiratory events: one negative night may not be enough. Chest 2000; 118:353–359

20 Whittle AT, Finch SP, Mortimore IL, et al. Use of home studies for diagnosis of the sleep apnea/hypopnea syndrome. Thorax 1997; 52:1068–1073

21 Redline S, Tosteson T, Boucher MA, et al. Measurement of sleep-related breathing disturbances in epidemiologic studies: assessment of the validity and reproducibility of a portable monitoring device. Chest 1991; 100:1281–1286

22 Kiely JL, Delahunty C, Matthews S, et al. Comparison of a limited computerized diagnostic system (ResCare Autoset TM) with polysomnography in the diagnosis of obstructive sleep apnea syndrome. Eur Respir J 1996; 9:2360–2364

23 Middelkoop HAM, Neven AK, Hilten JJ, et al. Wrist actigraph assessment of sleep in 116 community based subjects suspected of obstructive sleep apnea syndrome. Thorax 1995; 50:284–289

24 Kapur V, Blough DK, Sandblom RE, et al. The medical cost of undiagnosed sleep apnea. Sleep 1999; 22:749–755

25 Esnaola S, Duran J, Infante-Rivard C, et al. Diagnostic accuracy of a portable recording device (MESAM 4) in suspected obstructive sleep apnoea. Eur Respir J 1996; 9:2597–2605

26 Cirignotta F, Mondini S, Gerardi R, et al. Unreliability of automatic scoring of MESAM 4 in assessing patients with complicated obstructive sleep apnea syndrome. Chest 2001; 119:1387–1392

27 Pitson DJ, Stradling JR. Autonomic markers of arousal during sleep in patients undergoing investigation for obstructive sleep apnoea, their relationship to EEG arousals, respiratory events and subjective sleepiness. J Sleep Res 1998; 7:53–59

28 O'Donnell CP, Allan L, Atkinson P, et al. The effect of upper airway obstruction and arousal on peripheral arterial tonometry in obstructive sleep apnea. Am J Respir Crit Care Med 2002; 166:965–971

29 Pillar G, Bar A, Schnall R, et al. Autonomic arousal index: an automated detection based on peripheral arterial tonometry. Sleep 2002; 25:543–549