

Evaluation of a Portable Monitor (Watch-PAT100) and Implications for Clinical Guidelines for the Use of Portable Monitors in Diagnosing OSAS

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Abstract: *Objective:* To evaluate, industry independently, the accuracy of the Watch-PAT100 system (WP100) [Itamar Medical; Caesarea, Israel], a portable home sleep test, compared to polysomnography, the gold standard for diagnosing obstructive sleep apnea syndrome.

Methods: Prospective clinical trial. 27 patients (24 male, 3 female) were evaluated at our institution's sleep laboratory. The apnea hypopnea index and oxygen desaturation index were used to compare the 2 testing modalities.

Results: Non-parametrical testing showed a Kendall's tau = 0.685 for apnea hypopnea index and 0.748 for oxygen desaturation index. We found that the WP100 system overestimated the severity of obstructive sleep apnea syndrome in 33% when compared to polysomnography. The test-agreement was in particular poor when the WP100 indicated moderate to severe obstructive sleep apnea syndrome.

Conclusion: The WP100 seems accurate for classification of obstructive sleep apnea syndrome severity up to a WP100-measured apnea hypopnea index of 15. In patients with an apnea hypopnea index of more than 15 as measured with the WP100, additional polysomnography should be performed.

Keywords: Obstructive sleep apnea syndrome, polysomnography, monitoring sleep, ambulatory monitoring.

INTRODUCTION

Obstructive sleep apnea syndrome (OSAS) is characterized by recurring episodes of complete or partial upper airway collapse during sleep, resulting in snoring and apneas or hypopneas. It is a common disorder in the middle-aged (30-60 years) and affects 4% of men and 2% of women [1]. Its occurrence may be underestimated because of the worldwide increasing prevalence of obesity, the major risk factor for developing OSAS [2]. However, also in the non-obese OSAS has a high population prevalence. It has been estimated that even in a population with access to a sleep disorders clinic at least 80% of all moderate to severe OSAS patients remain undiagnosed. This was found to be the case especially for people with lower socioeconomic status, non-whites and women [3]. Accurate and timely diagnosis for patients with OSAS is imperative since severe OSAS increases the risk of morbidity and mortality from cardiovascular disease [4,5] and traffic accidents [6,7].

History and physical examination cannot reliably diagnose OSAS [8-11] and the gold standard for diagnosing OSAS is polysomnography (PSG), preferably the attended overnight polysomnogram [12]. However, the growing interest in OSAS has resulted in increased requests and

waiting lists for polysomnography, as well as a potential delay in diagnosis and treatment.

Bar *et al.*, introduced a portable device for unattended home sleep studies in 2003, called the Watch-PAT100. It continuously records arterial oxygen saturation, pulse rate, and actigraphic signal to identify sleep-wake states and a peripheral arterial tone (PAT) signal [13]. Several studies have explored its validity by comparing its results to either the in-lab or the ambulatory PSG [13-16]. However, these were all industry supported studies, and some publication bias can not be excluded. One study, industry independently, did try to compare the Watch-PAT100 (WP100) to the polysomnography. However, in this study patients underwent portable monitoring using WP100 at 1 month after full polysomnographic evaluation [17]. Because of night-to-night variability these data might not be comparable.

In the clinical guidelines for the use of unattended portable monitors for diagnosing OSAS it is stated that in patients with a high pretest probability of moderate to severe OSAS portable monitoring may be used to diagnose patients [18].

Routing of patients with OSAS after intake in our centre is determined by the classification of the severity of the disorder based on the overnight apnea hypopnea index (AHI). The main objective of the study was to evaluate whether WP100 AHI results could be used interchangeably with PSG results in the initial classification of patients.

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Correct classification of OSAS severity is of utmost importance since individual treatment plans are based upon OSAS severity.

MATERIALS AND METHODOLOGY

Study Design

Consecutive patients who were referred to the Department of Otorhinolaryngology, Head and Neck Surgery of the Sint Lucas Andreas Hospital (Amsterdam, The Netherlands) because of combined complaints of excessive daytime sleepiness, snoring and witnessed apneas in the period November 2006 to May 2007, were invited to undergo simultaneous Watch-PAT100 and polysomnography recordings in-hospital. Patients suffering from diabetes or hypertension and patients using antihypertensive drugs were excluded. Use of sleep medication and alcohol was prohibited on the day of investigation. Subjects had to give their written informed consent prior to participation. The study was approved by the local human research ethics review board.

Polysomnography

Polysomnography (PSG) was recorded using a digital polygraph system (Embla, Flaga Medical Devices, Reykjavik, Iceland) (Fig. 1). Electroencephalogram (FP2-C4/C4-O2), electrooculogram and submental electromyogram were used to record the sleep pattern. Nasal airflow was measured by a pressure sensor. Thoracoabdominal excursions were recorded by straps containing piezoelectric transducers (Embla). Pulse oximetry (Nonin 8000J) was used to monitor oxygen saturation (SaO₂) and pulse rate. In addition, electrocardiogram, movements of the limbs and the intensity of snoring were recorded. Electrodes and sensors were placed according to a standard protocol and equipment was calibrated. The system was automatically switched on at 8 pm and off at 8 am. All signals were recorded with DDD (digital sampling, digital filtering, digital storage) recording technology. The following day, data were downloaded to the computer and analyzed automatically by dedicated sleep software (Somnologica). The automated results of the entire PSG were visually verified, and if necessary corrected, by an experienced sleep investigator for final analysis.

Watch-PAT100

The forearm-worn Watch-PAT100 (WP100) system (Itamar Medical Ltd., Caesarea, Israel) has been thoroughly described elsewhere [13-16]. The WP100 measures peripheral arterial tonometry combined with oximetry and actigraphy (a movement measurement). It correlates changes in finger pulse pressure (modulated by sympathetic nervous output), pulse rate, oximetry, and actigraphy with proprietary signal analysis, and it provides estimates of the apnea hypopnea index (AHI), respiratory disturbance index, oxygen desaturation index (ODI), sleep duration and the occurrence of REM sleep.

It consists of a mounting sleeve, the WP100 device, a PAT probe and a pulse oximeter sensor (Nonin 8000J). The WP100 device itself contains an actigraph, a rechargeable power supply and data storage on a CompactFlash card



Fig. (1). Volunteer demonstrating digital polygraph system.

(Fig. 2). An experienced sleep investigator showed how to mount the WP100 system on the subject's arm. After this the WP100 instruction video was shown. The WP100 was attached to the non-dominant arm. Oximeter was placed on the ring finger, PAT-probe was placed on the index finger. Patients were told to switch on the device when they were about to sleep. On the next morning, all data were uploaded and automatically analyzed by the commercial software (zzzPAT, version 44, Itamar Medical Ltd.) without manual adjustments. The Watch PAT software uses an automatic algorithm based on the PAT signal amplitude, pulse rate and oxygen saturation. Sleep/wake detection is based on data recorded by the built-in actigraph.

Definitions

In PSG recordings arousal was defined as abrupt shifts from sleep (of at least 10 seconds duration) to faster EEG activities. Apnea was defined as cessation of airflow for ≥ 10 seconds. Hypopnea was defined as a reduction of airflow for ≥ 10 seconds associated with at least a 30% reduction in thoraco-abdominal movement of airflow and with at least 4% oxygen desaturation or the presence of an arousal. Apnea hypopnea index (AHI) was defined as the total number of apneas plus hypopneas divided by total sleeping time. In concordance with present Dutch OSAS classification standards an AHI between 5 and 15/h was considered mild, between 15 and 30/h moderate and above 30/h severe OSAS



Fig. (2). Volunteer demonstrating WP100 system.

[19,20]. Oxygen desaturation index (ODI) was calculated as the number of oxygen desaturations of at least 4% per hour of sleep.

The WP100 system uses a proprietary algorithm to determine above mentioned sleep parameters based on variations in peripheral arterial tone, pulse rate, oxygen saturation and actigraphy.

Data Analysis

Continuous variables were expressed as means ± standard deviation. Pearson correlation tests and non-parametric tests (Kendall’s tau) were used to test the AHI and ODI correlation between the WP100 and PSG. Thresholds of PSG AHI <5, 5-15, 15-30 and >30/h were used as different cut-off points for OSAS diagnosis. All statistical tests were carried out using SPSS 17.0 (SPSS Inc., Chicago, IL), and a p-value of .05 or less was considered statistically significant.

RESULTS

Instructing patients on how to use the WP100 was easy and little time consuming (5-10 minutes). Placement of polysomnography (PSG) electrodes and sensors and calibrating the equipment was more time consuming (40 minutes). Patient WP100 data were automatically analyzed without manual adjustments (2 minutes per subject). Patient PSG data were manually reviewed by an experienced sleep investigator for further analysis (60 minutes per subject).

Table 1. Baseline Characteristics of All Patients (n=27)

Patient Characteristics	
Age (years)	45.8 ± 9.4
Body mass index (kg/ m ²)	29.5 ± 5.7
Male : female ratio	8 : 1

Age and body mass index are shown as mean ± standard deviation.

Table 1 shows the baseline characteristics of the patients. The majority of the study population consisted of middle-aged, overweight men. The distribution of the AHI recorded by polysomnography (AHI_{PSG}) is shown in Fig. (3).

The horizontal axis depicts the cut-off AHI value corresponding to the bar. Using AHI PSG 5 as the cut-off value, the prevalence of OSAS in this population was 81.5%.

Table 2 shows the sleep and breathing characteristics comparing PSG and WP100. The mean AHI PSG of the study population was 23.6 ± 4.5 events per hour. The median AHI PSG was 12.0 consistent with a skewed distribution of AHI values. The mean AHI recorded by Watch-PAT100 (AHI_{WP100}) was 31.1 ± 4.9, the median was 18.6. The correlation between the AHI_{PSG} and AHI_{WP100} (r = 0.928 [n = 27], p < 0.01) was good (Fig. 4A).

The correlation was even better for the oxygen desaturation index as measured by PSG (ODI_{PSG}) and by WP100 (ODI_{WP100}) (r = 0.955 [n = 26], p < 0.01) (Fig. 4B).

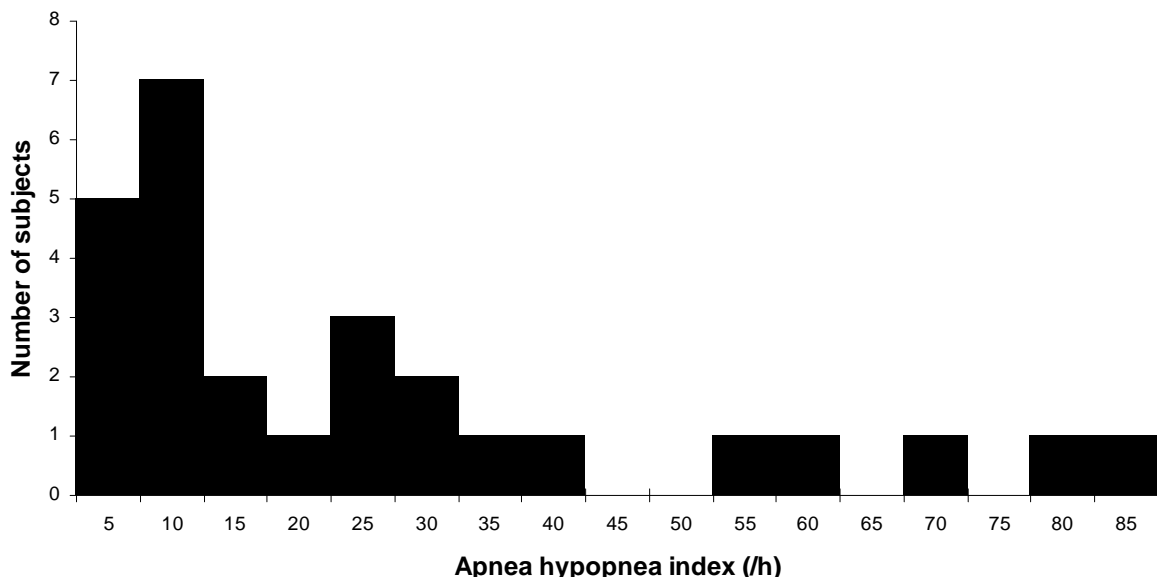


Fig. (3). Distribution of the apnea hypopnea index as recorded by polysomnography (n=27).

Table 2. Sleep and Breathing Characteristics Comparing PSG and WP100 (n=27)

Sleep Parameter	Polysomnography	Watch-PAT100
Apnea hypopnea index (/h)	23.6 ± 4.5 (12.0)	31.1 ± 4.9 (18.6)
Oxygen desaturation index (/h)*	18.0 ± 4.8 (5.1)	21.0 ± 4.6 (10.7)

Data are presented as mean ± standard error of the mean events per hour. Median is shown between parentheses.

PSG = polysomnography

WP100 = Watch-PAT100

*The data of 26 subjects were used to perform the oxygen desaturation index comparison.

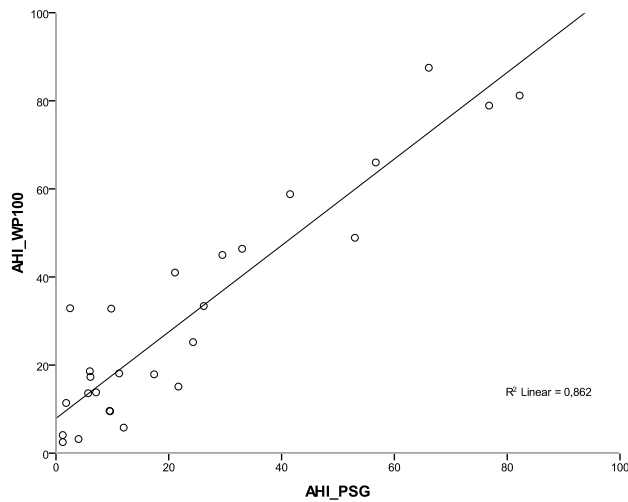


Fig. (4A). Scatter plot of apnea hypopnea index by device (n=27). Values on the horizontal axis represent polysomnography (PSG) data. Watch-PAT100 (WP100) data are shown on the vertical axis. AHI=apnea hypopnea index (/h).

However, this correlation could be influenced by the skewed distribution of the data. Therefore, additionally, we tested non-parametrical relations which showed a slightly less favourable result (Kendall’s tau = 0.685 for the AHI data and 0.748 for the ODI data).

Even with a perfect correlation the question would still remain whether the Watch-PAT100 measured AHI data were sufficient to classify the severity of OSAS correctly using the standard cut-off criteria.

Fig. (5) shows the classification of OSAS severity using the WP100 system. 12 out of 27 (44.4 %) patients would have been diagnosed to have a severe OSAS. Apart from showing the distribution in severity of OSAS using the WP100, the bars also show how each individual patient was classified using the PSG AHI data. 5 out of 12 patients diagnosed as having a severe OSAS according to the WP100 were diagnosed as having a less severe or even no OSAS using the PSG. 3 out of 6 patients diagnosed as having a moderate severe OSAS according to the WP100 were diagnosed as having a less severe OSAS using the PSG. 8 out of 18 patients (44%) diagnosed as having a moderate severe to severe OSAS using the WP100 had an overestimation of their OSAS severity. These results are also summarized in Fig. (6). In the total group of patients 9 out of

27(33%) had an overestimation of their AHI by WP100 leading to a different OSAS severity classification.

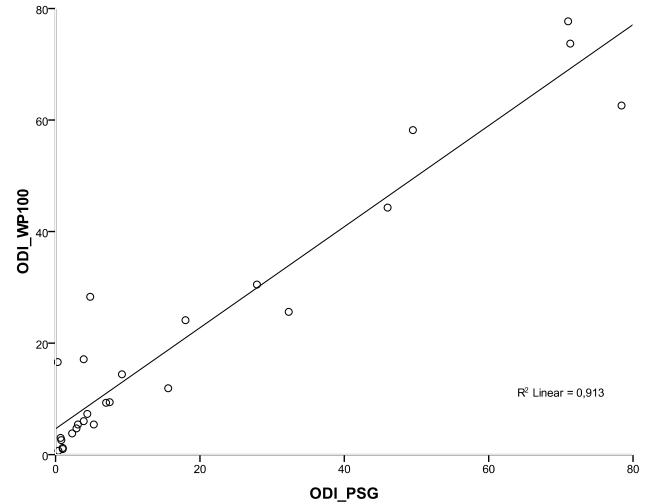


Fig. (4B). Scatter plot of oxygen desaturation index by device (n=26). Values on the horizontal axis represent polysomnography (PSG) data. Watch-PAT100 (WP100) data are shown on the vertical axis. ODI=oxygen desaturation index (/h).

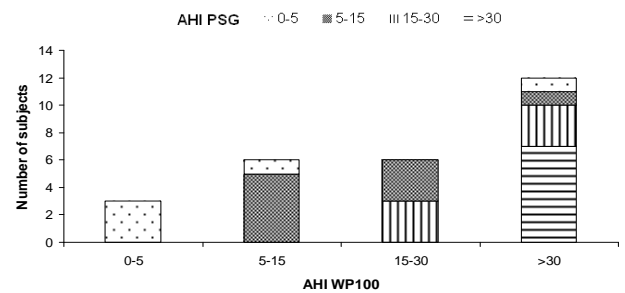


Fig. (5). Classification of OSAS severity using Watch-PAT100 system. AHI PSG= apnea hypopnea index (/h) measured by polysomnography. AHI WP100= apnea hypopnea index (/h) measured by Watch-PAT100 system.

DISCUSSION

Obstructive sleep apnea syndrome (OSAS) affects millions of people worldwide and is increasingly recognised as a major health problem in different countries [21-23]. Severe OSAS increases the risk of morbidity and mortality from cardiovascular disease [4,5] and traffic accidents [6,7]. Since the major risk factor for developing OSAS, obesity, is an increasing problem in many countries the prevalence of OSAS will continue to rise [2].

The gold standard for diagnosing OSAS, polysomnography (PSG), is relatively expensive, technically complex, labour intensive and cumbersome [12,24].

Portable devices to screen for sleep disordered breathing have been introduced almost 30 years ago [25] and have been classified according to the approach used in the 1994 American Sleep Disorders Association review. Type 1 is the standard PSG, while type 2 monitors incorporate a minimum of seven channels. Type 3 monitors incorporate a minimum of four monitored channels, including ventilation or airflow, pulse rate or ECG and oxygen saturation. The remaining portable devices are grouped as type 4 [24]. The Watch-

PAT100 system (WP100) would be classified a type 3 monitor.

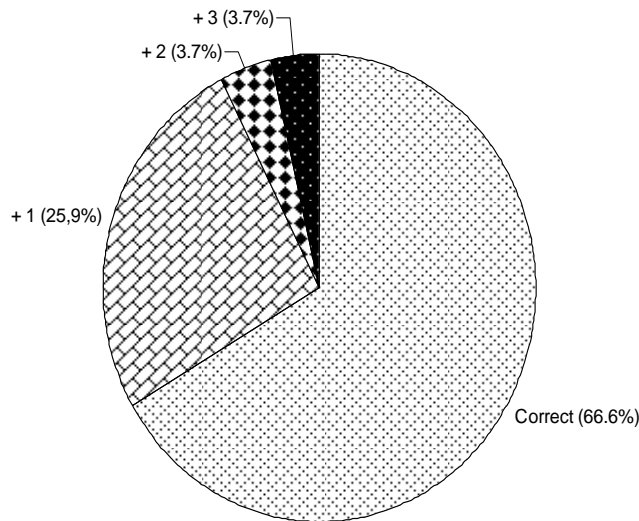


Fig. (6). Classification of OSAS severity using Watch-PAT100 system. + 1, 2, 3 depicts the number of OSAS category overestimations in each individual patient. The percentage of each different group is displayed between parentheses. OSAS = obstructive sleep apnea syndrome.

Clinical guidelines for the use of unattended portable monitors in the diagnosis of OSAS have been introduced in 2007 by the American Academy of Sleep Medicine (AASM) [18]. AASM recommends that such devices should record airflow, respiratory effort and blood oxygenation. The WP100 is not classified as such a cardiorespiratory monitor. However, the committee felt that the device was at least equivalent to available cardiorespiratory monitors. In these guidelines and in the health care guidelines compiled by the Institute for Clinical Systems [26], it is stated that in patients with a high pretest probability of moderate to severe OSAS portable monitoring may be used as an alternative to polysomnography. When in these selected patients OSAS has been diagnosed, treatment should be initiated.

This study shows that the WP100 is an easy to use portable device. It has a good instructional video on how to use the device and it takes less time to have the data analyzed automatically compared to our manually executed PSG analyses. At first sight correlation seems very good ($r = 0.928$) between the AHI WP100 and the AHI PSG. This correlation is even better for the ODI data ($r = 0.955$). However, the data distribution in our study was skewed. Non-parametrical testing showed a less favourable result (Kendall's tau = 0.685 for the AHI data and 0.748 for the ODI data). (Note that the tau value can not be considered equivalent to the Pearson r value). The classification of OSAS severity (scaled as 5-15, 15-30 and >30 , for mild, moderate and severe OSAS, respectively) based upon the AHI WP100 showed a large portion (33%) of overestimation when compared to the AHI PSG. One patient who didn't

suffer from OSAS according to the PSG data had a severe OSAS (AHI > 30) according to the WP100 system (+ 3 in Fig. 6). When clinical guidelines would be applied such patients diagnosed with WP100 only, would be unnecessarily treated or overtreated.

Some potential limitations of this study need to be discussed. The clinical guidelines advice that a portable monitor should "allow for the display of raw data with the capability of manual scoring or editing of automated scoring by a qualified sleep technician/ technologist" [18]. In the WP100, this is not possible. WP100's successor, the Watch-PAT200 (introduced in 2008), does however, have the function of manually editing the suggested automatic analysis. It also features measuring body position and snoring [27]. We have no research experience with the WP200 with these added features so far.

CONCLUSION

The Watch-PAT100 (WP100) is an easy to use portable device for unattended home sleep studies. It showed accurate oxygen desaturation indices. Our study showed moderately correlating apnea hypopnea indices (AHI) when compared to polysomnography data in a high pretest probability of moderate to severe obstructive sleep apnea syndrome (OSAS) patient group. However, severity of OSAS cannot be estimated accurately by the WP100. In patients with AHI values higher than 15 as measured by WP100, an additional polysomnography should be performed in order to prevent overtreatment. Future research, preferably industry independent, on using a portable monitor in diagnosing OSAS is needed to be able to draw more evidence based conclusions and review the current clinical guidelines on its use.

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CONFLICT OF INTEREST

Declared none.

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