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ORIGINAL RESEARCH—SLEEP MEDICINE

A comparison of polysomnography and the WatchPAT in the diagnosis of obstructive sleep apnea

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OBJECTIVE: Our goal was to validate the WatchPAT in the diagnosis of obstructive sleep apnea.

STUDY DESIGN: We conducted a prospective, blinded, nonrandomized clinical trial.

METHODS: Patients with suspected obstructive sleep apnea scheduled for an overnight level I polysomnogram were offered enrollment in a study to compare the WatchPAT (Itamar Ltd, Israel) device with polysomnography. Patients wore the WatchPAT device simultaneously while undergoing polysomnography during evaluation in the sleep lab.

RESULTS: Thirty-seven patients participated in the study. They had a mean age of 50.1 years (range, 31−73 years) and mean body mass index of 34.6 kg/m^2 (range, 21.2−46.8 kg/m^2). There was high correlation between the polysomnogram and WatchPAT apnea-hypopnea index ($r = 0.9288$; 95% confidence interval = 0.8579−0.9650, $P < 0.0001$). The lowest oxygen saturation also showed high correlation ($r = 0.989$; 95% confidence interval = 0.9773−0.9947, $P < 0.0001$). The overall polysomnogram and WatchPAT sleep times revealed a correlation of $r = 0.5815$ ($P = 0.005$).

CONCLUSION: The WatchPAT showed a high correlation with the polysomnogram in apnea-hypopnea index, lowest oxygen saturation, and sleep time.

SIGNIFICANCE: It's use as a reliable tool in the diagnosis of Obstructive Sleep Apnea.

Vibration of the structures in the oral cavity and oropharynx—the soft palate, uvula, tonsils, base of tongue, epiglottis, and pharyngeal walls—results in snoring. Most believe that it may represent an alarm to alert one to the possibility of a sleep disorder. Sleep disordered breathing (SDB) is a spectrum of diseases that includes snoring, upper airway resistance syndrome, and obstructive sleep apnea (OSA). OSA is a common sleep disorder; Young et al[1] studied 602 state employees who underwent formal overnight polysomnography and found that the incidence of SDB was 24% in men and 9% in women. Most of these patients are undiagnosed. It is estimated that up to 93% of females and 82% of males with moderate to severe OSA remain undiagnosed.[2]

The spectrum of sleep-related breathing disorders is related to reduced airflow through the upper airway during sleep, due either to complete or partial upper airway obstruction or to increased upper airway resistance. These include simple snorers (snorers who have no daytime somnolence and with a normal apnea-hypopnea index [AHI]), those with upper airway resistance syndrome (UARS) (snorers who have daytime somnolence but have a normal AHI), and those with OSA (snorers who both are tired and have an abnormal AHI). At night, this would result in poor sleep quality, fragmented sleep, intermittent nighttime hypoxemia, reduced percentage of slow-wave sleep, and increased sympathetic overdrive. These then translate into daytime somnolence, morning headaches, poor concentration, memory loss, frustration, depression, and even marital discord. Due to the sympathetic overdrive, sleep fragmentation, and intermittent nocturnal hypoxemia, there is added stress on the cardiovascular system, and systemic hypertension may result.

The Sleep Heart Health Study and the Wisconsin Sleep Cohort[3,4] have demonstrated a strong link between SDB and hypertension. There is also convincing evidence of the association between SDB and cardiovascular disease.[5] There is a higher mortality rate among patients with cardiovascular disease who also have SDB.[6,7] An essential public health priority is the diagnosis of all patients with OSA, to prevent the development of severe cardiovascular morbidity and mortality.

The gold standard for the diagnosis of OSA remains the attended overnight level I polysomnogram (PSG). However, these studies have limited resources, including recording beds, high cost, long waiting lists, and intense labor requirements. Moreover, elderly or sick patients often find the PSG equipment too cumbersome and may be reluctant to spend the night in the sleep laboratory. Single and multiple channel monitoring systems have been introduced to screen for OSA.

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There are four levels of sleep testing:

- Level I: Attended overnight full polysomnography (includes electroencephalogram [EEG], electro-oculogram [EOG], electromyogram [EMG], electrocardiogram [ECG], oronasal airflow, thoracic and abdominal movement, oxygen saturation, snoring level, and body position)
- Level II: Unattended overnight full PSG (similar to level I study but conducted at the patient's home)
- Level III: Unattended limited PSG (usually includes only oronasal airflow, thoracic and abdominal movement, and oxygen saturation but may include snoring level and body position)
- Level IV: Unattended screening sleep study (very limited study, usually only oxygen saturation and oronasal airflow)

In general, to prevent technical problems, like electrodes falling off or malpositioning of the leads, most sleep authorities prefer the use of the attended overnight in-house PSG for the sleep test. Without the ability to monitor brain waves, one would not be able to tell if the patient actually slept or whether the patient had good, deep sleep; hence, most sleep authorities prefer a sleep test that is able to tell sleep efficiency and actual sleep time.

The ideal screening device for OSA should be inexpensive, widely accessible, easily used with minimal instructions, and accurate and have no risk or side effects to the patient. The current investigation proposes to validate the reliability and predictive capability of the WatchPAT device.

The WatchPAT monitors three main parameters: very simplistically, actigraph (monitors whether the patient is asleep or awake), peripheral arterial tone (reflects the sympathetic activity in the patient), and pulse oximetry (oxygen level in the blood). It works by correlating patient's low oxygen (oxygen desaturation) with his or her sympathetic tone (high, being a stressful obstructive event, and low, being a central apnea) and whether the patient is sleeping or awake (actigraph). From the data collected, one is able to determine if the patient's low oxygen is due to an obstructive event or central event, during the sleep state or awake state.

METHODS

Study Design

Thirty-seven consecutive adult patients referred to the Georgia Sleep Center for attended overnight level I polysomnography were prospectively enrolled over a 3-month period. All patients gave informed consent to wear the WatchPAT device simultaneously with the PSG during the same night in the sleep lab. The protocol was approved by the Institutional Review Board committee at the Medical College of Georgia.

Polysomnography

All patients underwent attended, overnight level I polysomnography in the hospital. Airflow during sleep was measured using standard nasal and oral thermistors. Two separate respiratory effort channels (thoracic and abdominal belts) were used, and body position was recorded. Sleep stage was evaluated with continuous monitoring of four EEG channels and two EOG channels. Other additional parameters monitored included EMG of the chin, ECG, limb movements, pulse oximetry, and snoring sound level. Polysomnographic variables assessed included sleep parameters, sleep staging, sleep time, sleep latency, sleep efficiency, rapid eye movement (REM) and non-REM events, arousals, respiratory events including the AHI, oxygen desaturations, snoring level, body position, and limb movements.

Respiratory events were scored as either apneas or hypopneas. An apnea was defined as cessation of airflow for $\geq$10 seconds. A hypopnea was defined as a reduction of airflow for $\geq$10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow and with at least 4% oxygen desaturation or the presence of an arousal. An arousal would be defined as an increase in EEG activity, usually alpha, more than three seconds on EEG in REM sleep and associated with increased EMG reading in non-REM sleep. The AHI is represented by the sum of the apneic and hypopneic events per hour of sleep. The sleep technologist and the board certified sleep physician scored all the PSGs.

WatchPAT

The WatchPAT is a screening device that uses two noninvasive self-adhesive finger probes that measure pulse oxymetry and peripheral arterial tonometry (PAT). The PAT technology is a unique and relatively new concept of noninvasive measurement of sympathetic activation levels that is accurate for detecting SDB events. This is a self-contained device worn around the wrist. The pressurizing mechanism of the probe allows it to be lightweight and silent, essential for a practical ambulatory device. Two finger probes extend from the main body of the device. One is the opticopneumatic sensor that detects the PAT signal; the other measures arterial oxygen saturation. The body of the device also contains an actigraph (three-axis accelerometer for detection of limb activity), which is used to differentiate sleep from wakefulness. This technology uses a finger-mounted optic/pneumatic sensor that eliminates venous pulsations and continuously measures the pulse volume of the digit. Episodic vasoconstriction of digital vascular beds from sympathetic stimulation (mediated by alpha receptors) will result in attenuation of the signal. Because discrete obstructive airway events (e.g., apneas, hypopneas, and upper airway resistance) cause arousal from sleep, sympathetic activation, and peripheral vasoconstriction, these events are associated with attenuation of the PAT signal. An automated computerized algorithm is used to calculate the

frequency of respiratory events per hour of actigraphy measured during sleep. This also combines the PAT signal attenuation and the oxygen desaturation. With these signals, the device is able to record the number of obstructive events associated with oxygen desaturation. Total sleep time and REM percentage are also recorded. Based on all the data that the WatchPAT records, it produces a comprehensive report on the AHI and the respiratory disturbance index (RDI), which includes the number of respiratory-related arousals (RERAS). The results of the data are interpreted with use of Itamar Ltd proprietary software.

All of the patients' results were read independently by two of the authors who were blinded to the results of the corresponding PSG and the WatchPAT.

Statistics

We used the Pearson's correlation to compare data from the PSG and the WatchPAT. We looked at the correlation between their respective results, namely, AHI, sleep time, lowest oxygen saturation (LSAT), REM percentage, and oxygen percentage.

RESULTS

A total of 37 patients (12 men and 25 women) were recruited for the study, the mean age was 50.1 ± 12.2 years (range, 31−73 years), and the mean BMI was 34.6 ± 5.2 kg/m^2 (range, 21.2−46.8 kg/m^2). The mean Epworth Sleepiness Scale score was 13.9 ± 3.7 of a possible 24 (range, 2−20). There were five patients with an inadequate sleep time, and therefore they were excluded from the study. The mean AHI for the PSG was 34.87, while the mean AHI recorded was 35.10 on the WatchPAT data. The mean LSAT was 82.03% recorded on the PSG, while the mean LSAT was 81.46% noted on the WatchPAT. The mean total sleep time (TST) for the PSG was 5.65 hours, while that of the WatchPAT was 5.33 hours. There was high correlation between the PSG and WatchPAT AHI ($r = 0.9288$; 95% confidence interval [CI] = 0.8579−0.9650, $P < 0.0001$). The LSAT also showed high correlation ($r = 0.989$; 95% CI = 0.9773−0.9947, $P < 0.0001$) (Table 1). The overall PSG and WatchPAT sleep times revealed a correlation of $r = 0.5815$ ($P = 0.005$). Calculating sensitivity and specificity at each level, the sensitivity of detecting a patient with OSA at AHI greater than 5 was 0.94 and a specificity of 0.80. At an AHI >15, the sensitivity was 0.96 and the specificity was 0.79. The sensitivity of detecting a patient with severe AHI was 0.83 with a specificity of 0.72 (Table 2).

Table 1
Showing correlations between the PSG and the WatchPAT data

	PSG	WatchPAT	Correlation	*P* value
AHI	34.87 ± 20.2	35.10 ± 25.1	$r = 0.9288$	<0.0001
LSAT	82.03 ± 15.1	81.46 ± 16.2	$r = 0.9891$	<0.0001

AHI, apnea-hypopnea index; *LSAT,* lowest oxygen saturation.

Table 2
Sensitivity and specificity of the WatchPAT with PSG

	Sensitivity	Specificity
AHI >5	0.94	0.80
AHI >15	0.96	0.79
AHI >35	0.83	0.72

AHI, apnea-hypopnea index.

DISCUSSION

SDB is a chronic, debilitating disease that results in significant cardiovascular and cerebrovascular morbidity and mortality. Marti et al[8] showed that the mortality rate for untreated severe OSA was 23.5% in a 10-year follow-up. Mortality was mainly due to cardiovascular and respiratory causes. OSA, when undiagnosed, results in significantly higher medical costs compared with age- and sex-matched patients who are diagnosed. Kapur et al[9] report that untreated OSA may cost the U.S. health care system up to $3.4 billion annually. This great financial burden justifies the search for an inexpensive and straightforward means for diagnosing OSA, such as portable home screening devices.

Ayas et al[10] found in 30 patients a good correlation of $r = 0.87$, $P < 0.001$, between the WatchPAT and the gold standard PSG. Pillar et al[11] also showed similar results in 68 patients who underwent the overnight PSG and the WatchPAT simultaneously, on the same night ($r = 0.87$, $P < 0.001$). Bar et al[12] revealed impressive results in 102 patients; they found that across a wide range of RDI levels, the WatchPAT RDI 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 WatchPAT RDI scores were also highly reproducible, showing high correlation between home and in-laboratory sleep studies ($r = 0.89$, $P < 0.001$).[12] Schnall et al[13] found a high correlation between standard polysomnography scored apnea-hypopnea events and PAT-vasoconstriction events with concurrent tachycardia in an initial study with the bedside version of the system. Pillar et al[14] showed that detection of apnea and hypopnea events based on combined data from PAT and pulse oximetry was highly correlated with standard polysomnographic scored results, a finding that was confirmed by Pittman et al[15] using both manual and automatic analysis. O'Donnell et al[16] further explored the PAT

response in patients with OSA. They experimentally induced upper airway obstruction and showed that airflow obstruction in patients with OSA leads to a PAT signal attenuation in a "dose-response" manner; that is, greater airflow obstruction causes greater PAT attenuation.

Our data showed that there was a good correlation between the polysomnography and the WatchPAT, with a correlation of $r = 0.9288$ (95% CI = 0.8579−0.9650, $P < 0.0001$). The LSAT also showed high correlation ($r = 0.989$; 95% CI = 0.9773−0.9947, $P < 0.0001$). The correlation of the time spent below 90% oxygen saturation between the PSG and the WatchPAT showed a correlation of $r = 0.913$ (95% CI = 0.893−0.956, $P < 0.0001$). The overall PSG and WatchPAT sleep times had a correlation of $r = 0.5815$ ($P = 0.005$).

In this current study, both the WatchPAT and the PSG were conducted on the same night simultaneously, thereby eliminating the possibility of night-to-night variation. Both the principal investigator and the sleep physician were blinded to the results of the respective sleep test, in order to eliminate bias. Another limitation that merits consideration that is inherent in most home monitoring devices, but not the WatchPAT, is the fact that the total sleep time for the portable home device may not reflect the true sleep time. This represents a great advantage in the WatchPAT; through its actigraphy and arterial tone monitoring, it is able to detect sleep-wake phases and REM stages. However, we acknowledge that the apnea and hyponea events on the Watch PAT could not be counted simultaneously and correlated with that of the level I PSG.

CONCLUSION

Given the high prevalence of OSA and limited capacity for sleep laboratory testing, there is a clear need for home diagnostic devices. The WatchPAT is small, lightweight, inexpensive, reliable, accurate, easy to use, and safe. It also demonstrates high correlation with the gold standard polysomnogram (PSG).

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FINANCIAL DISCLOSURE

David Terris, MD, is a medical advisor for Apneon, Inc., and Aspire, Inc.

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