The Use of WatchPAT™ for Home Sleep Testing Assessment of Sleep-Related Disordered Breathing (SDB) in Heart Disease Patients – Clinical & Operational Benefits

Ilana S. Hairston, PhD
Senior lecturer, Tel Hai Academic College

INTRODUCTION

Sleep-related disordered breathing (SDB), specifically obstructive sleep apnea (OSA), is associated with a range of other physiological disorders, cardiovascular diseases being the most salient and life threatening among them; hence the inclusion of SBD as an independent cardiovascular risk factor has been proposed [1]. Abnormal respiratory patterns (e.g. apneas and hypopneas) and insufficient ventilation during sleep, which constitute SDB, affect approximately 10-25% of middle-aged and older adults, with significantly higher incidences among patients with CVD. The elevated risk for CVD and increased incidence of OSA among CVD patients are likely due to the acute and long term harmful effects of SDBs on cardiovascular functioning. Acutely, apneaic events cause hypoxemia and hypercapnia, extreme fluctuations in heart rhythms and blood pressure, fluctuations in intrathoracic pressure and micro-arousals. Long term, individuals with SDB may develop hypertension, atrial fibrillation, myocardial infarction, stroke, heart failure, as well as experience cognitive decline [2]–[4]. Importantly, the presence of SBD may impede rehabilitation after cardiac events, increasing the risk of patients for complications and future events [5].

This increased risk has led to a new focus on detection of sleep disturbances early in the cardiac disease progression process, and an emphasis on treating OSA to improve treatment outcomes and reduce risk for recurrence of future events [6].

Thus, screening for SDB has been recommended for patients entering cardiac practices. However, this recommendation is often met with the objection of providers and patients due to costly and cumbersome sleep laboratory-based polysomnography (PSG) assessment, considered the gold standard for the diagnosis of sleep disorders. In recent years, however, a variety of home sleep apnea testing (HSAT) devices have become available to clinicians and patients for the assessment of SDB at home, thereby minimizing the cost and discomfort associated with the full PSG protocol. HSATs have been used in non-clinical settings for determining the presence and severity of OSA for more than three decades, while recent technological advancements have made HSAT devices a viable alternative for clinical diagnosis of OSA in the patients' home. Beyond the reduced cost, being conducted in the patient's home for multiple nights, HSATs have the benefit of achieving a more representative assessment of patients' sleep patterns. Among these HSAT devices, WatchPAT is unique, relying (among additional channels) on the novel PAT signal which reflects autonomic nervous system functioning, and is by far the most studied, validated and published HSAT device [7]–[14]. It is a simple to use and cost-effective device, with high diagnostic accuracy and reliability. The aim of this review is to offer an in-depth description of WatchPAT benefits.

BACKGROUND

WatchPAT is an FDA-approved portable diagnostic device that enables accurate assessment of SDB suitable for home testing, which offers users substantial clinical and operational benefits, without sacrificing diagnostic accuracy, setting it apart from other HSAT devices.

Following is a point-by-point description

of WatchPAT's attributes.

What does WatchPAT do?

- WatchPAT is a non-invasive home care device for use with patients suspected of having sleep related breathing disorders. It is an easily applied, wrist-worn, device with a single thimble-like biosensor that is placed on the any one of the fingers, excluding the thumb.
- WatchPAT utilizes Peripheral Arterial Tone (PAT) signal that identifies changes in arterial pulsatile volume at the finger, that is regulated by α-adrenergic innervation of the smooth muscles of the finger's vasculature. Changes in PAT signal reflect surges in sympathetic nervous system activity associated with termination of apnea/hypopnea events, and therefore considered a reliable detector of these events [15], [16].
- WatchPAT is equipped with snoring and body position sensors and new advanced algorithms that enable the distinction between Central Sleep Apneas (CSA) and Obstructive Sleep Apnea (OSA) [17], as well as the potential to identify Cheyne-Stokes respiratory patterns, characteristic of heart failure patients [18].
- WatchPAT intuitive operation makes it a viable HSAT device for diverse patient populations, as evidenced by the minimal failure rate (< 2%) during data acquisition and analysis [11], [19]. Additionally, equipped with a proprietary rechargeable Li ion battery, WatchPAT recording time capacity is up to 3 nights.

Accreditation and Validation

In 2007, the FDA cleared WatchPAT for HSAT [20]. Further, with more than 100 peer reviewed studies supporting its validity and reliability, in 2017, the American Academy of Sleep Medicine (AASM) included the PAT technology as technically adequate in their HSAT guidelines [21]. These studies demonstrated high degree of agreement between WatchPAT SDB indices – Respiratory Disturbance index (RDI) and Apnea/Hypopnea index (AHI) and the gold standard PSG assessment with high sensitivity and specificity across studies, depending on AHI thresholds and populations [10], [22], [23].

Diagnostic Accuracy

Among the different HSAT devices available on the market, **WatchPAT is the an advanced FDA cleared (non-EEG) device that reliably measures total sleep time [9]**. To accurately assess the severity of OSA, it is necessary to determine the number of events that occur while the patient is asleep. Most HSAT devices do not effectively differentiate between sleep and wake, and calculate AHI based on Total Recording Time (TRT) rather than Total Sleep Time (TST). If the patient has substantial periods of wakefulness during the night, typical HSAT devices may underestimate SDB, leading

inaccurate classification of the severity of the patient's disorder, and to misdiagnoses of up to 20% of patients [24]. Prolonged arousals frequently occur among patients suffering from insomnia, pain, nocturia, obesity, arrhythmia's symptoms and other conditions that cause nighttime awakenings, resulting in significant discrepancy between TST and TRT.

Detection of Sleep Stages – Significance for CVD

WatchPAT detects sleep stages [9], [25] providing valuable information for assessing the effects of SDB on sleep quality. In most patients, SDB events occur throughout the night during either REM or non-REM sleep stages, however for some patients OSA is predominantly REM-related. As REM sleep constitutes approx. 25% of total sleep time, patients with REM-related OSA have lower or even normal AHI scores and report milder daytime symptoms; as a consequence these patients may not complain of sleep difficulty despite significant fragmentation or deprivation of REM sleep, leading to a risky misdiagnosis [26]. Nevertheless, REM-related OSA has recently been implicated in increased risk for hypertension [27], [28], potentially due to the hemodynamic and sympathetic characteristics of REM sleep, of rapid fluctuations in blood pressure and heart rate and a reduction in the hypoxic and hypercapnic ventilatory drive. Hence, REM-related apnea/hypopnea events are associated with significantly greater oxygen desaturation compared with events in non-REM sleep [29]. Therefore, accurate detection of REM-related OSA can improve the management of SDB, especially for CVD patients.

Classification of Central vs. Obstructive Sleep Apnea

The Central Plus module of WatchPAT enables, the differentiation between CSA and OSA [17], [18]. Unlike OSA, CSA is characterized by the temporary withdrawal of central respiratory drive and the cessation of respiratory effort. Whereas OSA is common in the general population, CSA is more common in heart failure patients, occurring in about 35% of that population, and typically accompanied by Cheyne-Stokes respiration [4]. The presence of CSA and Cheyne-Stokes respiration contribute to increased morbidity and mortality in patients with heart failure.

Monitoring Treatment Efficacy

Thanks to WatchPAT's high accuracy and the fact that data collection is based on PAT technology, rather than airflow sensors, it has been shown in various studies to be more beneficial for detecting residual SDB in CPAP treated patients, proving helpful in developing more individualized treatments. For example, one study found that one in five subjects who reported residual daytime symptoms had moderate to severe SDB while using CPAP, even while the CPAP device failed to detect the presence of sleep apnea [30]. These finding underscore the necessity for follow-up with the clinician to optimize the prescribed pressure to achieve adequate airway patency throughout the sleep period at home.

WatchPAT can simplify pre-operative assessment for OSA

As OSA increases the risk of perioperative morbidity and mortality, due to difficulty in maintaining a patent airway

pressure, current guidelines of the Society of Anesthesiology, recommend preoperative evaluation of patients for the identification of OSA, including physical examination. It is recommended that this assessment occur long enough prior to surgery to allow for preparation of a perioperative management plan [31]. This recommendation is emphasized for CVD patients, given their high incidence of SBD, and for patients with morbid obesity, for whom the use of belts on chest and abdomen, to assess breathing effort, is particularly challenging. WatchPAT can provide a simple solution to address the need to assess SBD in the comfort of the patient's home, using the finger biosensor well before hospitalization.

Ease of Application and Usability

HSAT devices are the preferred solution for adolescents, disabled patients or patients who are unable to stay overnight in a sleep laboratory for various reasons. WatchPAT exemplifies this advantage due to its simple setup. Typical HSAT devices use nasal cannula and/or chest belts to monitor respiration. Such sensors are uncomfortable, thus lowering patient compliance, and are at greater risk of being displaced during sleep, resulting in less reliable data. As WatchPAT does not require nasal cannula or chest belts, failure rate of WatchPAT is less than 2% [11], [19], compared with other home oximetry device in which signal failure can be as high as 15% [32].

Taken together, WatchPAT allows for data collection of typical night's sleep, at the comfort of the patient's own home with minimal physical discomfort. Proving to be clinically advantageous in:

a. Patients with atypical nasal anatomy such as narrow nose bridge, chronic allergies, or being on oxygen assisted therapy who cannot tolerate or use air-flow cannula.
b. Patients with a large waist circumference, due to excess weight or pregnancy, for whom a belt-free device is more reliable, causing less discomfort. Specifically, WatchPAT was recently validated for use in 3rd trimester of pregnancy when SDB is prevalent and potentially associated with adverse outcomes for both mother and fetus [10].
c. Adolescents for whom sleeping outside the home is difficult, and for whom the signal most at risk of disruption, in unattended home studies, is the nasal flow [33].

Operational Simplicity and Safety

Implementation, operation and data acquisition

WatchPAT enables quick, simple and efficient workflow. Thanks to the stability of the finger PAT probe, the device provides reliable and continuous sleep study data, with key required clinical SDB indices. Data scoring is fully automated, eliminating the necessity for laborious manual scoring, thus saving valuable time and resources. Further, the simple and intuitive application of WatchPAT makes it easy to instruct patients how to administer the device and upload results, thereby increasing study completion rate and further contributing to efficiency and cost effective workflow.

CloudPAT Platform – HIPPA-Compliant Data Transfer System

CloudPAT is a HIPAA-compliant web-based cloud application that allows users to streamline their workflow

electronically, without having to operate or maintain an in-house solution. CloudPAT provides instant access to comprehensive study reports from any online location, as well as the option of sending studies for interpretation by a certified sleep physician.

Safety

No reports of adverse events, side effects, or unmet safety issues in either of these studies.

EXPANDING LABELING RANGE

In July 2016, following studies of WatchPAT in adolescents, the FDA cleared and expanded the indication for WatchPAT to be used for the diagnosis of OSA in adolescents age 12 to 17 [20]. This is an important addition to the currently limited array of home-based diagnostic technologies for children. WatchPAT safety and efficacy has been demonstrated with no reports of side effects or early termination due to inconvenience. PAT-AHI and PSG-AHI correlation $r= 0.92$, $p < 0.001$. Sensitivity and specificity correlation of 100% for AHI $\geq$ 10 [20], [34].

CONCLUSIONS

WatchPAT is the next generation, highly innovative, technology-based HSAT device. Continuously evolving and expanding its application range, it is the advanced FDA-cleared HSAT device that accurately measures TST and sleep stages without the use of EEG. With its simple and accessible application, and use of PAT technology, WatchPAT offers a diagnostic solution for a wide range of clinical needs, and diverse patient populations, including cardiac patients, overweight/obese patients, pregnant women, children, and in the community, for primary assessment of SDB and CPAP treatment efficacy.

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