SleepView™ Web-Based Software

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Abstract:

Study Objective: to assess the feasibility and accuracy of a web-based portable sleep monitor and scoring technology for sleep apnea evaluation in the home. **Introduction:** Sleep Disordered Breathing (SDB) affects more than 20 million patients with serious health and economic costs. Patient resistance to sleep outside of the home, long-term disease management, and reduced reimbursement emphasize the necessity for a simple and cost effective Home Sleep Testing (HST) solution. **Methods:** The technology consists of a web portal that facilitates data management including manual over-read and report generation. The web portal interfaces to a seven (7) channel HST monitor (SleepView) which follows the AASM channel set recommendations. The monitor incorporated two automated scoring algorithms: respiratory event detection and sleep time estimation. To assess feasibility and accuracy, the system was tested on 13 patients admitted for routine Polysomnography at the Cleveland Clinic. The morning after the PSG study, each patient was instructed on the sensor set-up and sent home with the monitor. Once the monitor is returned to the lab, data and morning questionnaires were uploaded to the webportal, scored automatically and manually over-read by a Registered Polysomnographic Technologist (RPSGT). **Results:** The patients found the device and sensor set-up easy to use with patients rating the "overall experience with SleepView use" either good or excellent. When compared to PSG, the monitor had AHI sensitivity of 100%, and specificity of 67%. These results did not change when the AHI calculation used Total Recording Time (TRT) instead of Total Sleep Time (TST). However, when compared to in-lab results, the at home AHI calculations that used TST generated a closer approximation (smaller bias) when compared to the calculations that used TRT (-3.9 vs. -5.6, $p<0.01$). This confirms the role of sleep time in improving disease *severity* assessment. **Conclusions:** a new web-based HST solution with an easy-to-use monitor, effective workflow and scoring solution was developed and tested successfully. At-home results showed strong correlation with PSG especially when TST was used in the AHI calculation. The monitor's accuracy is attributed to utilizing conventional in-lab signals and a scoring method that relies on event detection algorithms combined with manual over-read. The system lends itself for efficient and streamlined HST deployments that require seamless networking of multiple stakeholders such as sleep labs, family physicians, nurses and scorers.

Introduction:

Obstructive Sleep Apnea (OSA) occurs when the soft tissues of the upper airway collapse on inspiration and cause a partial or total cessation of airflow. There are many factors potentially involved in causing this airway collapse. They include enlarged tonsils, loss of tone in the oropharynx and palate, enlarged or posteriorly positioned tongue, fat in the pharyngeal tissue planes, and nasal obstruction causing turbulent flow through the upper airway. A report by the National Commission on Sleep Disorders Research (1) shows that 12-20 million Americans suffer from OSA leading to more than 200,000 car crashes per year and 1/3 of fatal trucking accidents due to fatigue. The financial cost impact is also staggering. Estimated direct annual cost for OSA is $16 billion (2,3). OSA has also been linked to cardiovascular and cerebrovascular implications making the disorder even more alarming than originally thought (4). In a study by Dyken et al., sleep apnea was five times as frequent in patients with ischemic or hemorrhagic strokes (5). Therefore, sleep disorders in general and OSA in specific present a serious national healthcare concern. One of the most important and widely used indicators of OSA severity is the Apnea Hypopnea Index (AHI), which is defined as the average number of apneas and hypopneas episodes per hour based on a minimum of 2 hours of recorded sleep. New regulations by the Center of Medicare and Medicaid Services (CMS) allowed the use of total recording time instead of total sleep time for ambulatory home studies since portable monitors do not typically record sleep state. In that case, the resultant output is named the Respiratory Disturbance Index (RDI). Typically, AHI (or RDI) > 30 indicates severe OSA, while mild to moderate OSA patients show AHI (or RDI) between 5 and 30. AHI < 5 suggests normal breathing and is typically a target for successful OSA therapy. According to AASM 2007 guidelines, apnea is defined as a 90% or more cessation of airflow for at least ten seconds, while hypopnea is defined as a drop of 50% or more in airflow for at least ten seconds combined with oxygen desaturations of 3% or more and at least 90% of the event's duration must meet the amplitude reduction for hypopnea.

Home Sleep Testing per AASM Guidelines

A task force assigned by AASM concluded that HST can indeed facilitate and improve patient care provided that HST is done according to specific guidelines, which include appropriate physiological signals, scoring done by registered sleep technologist and interpretation read by a sleep physician. The parameters recommended by the task force are: pulse oximetry, heart rate, airflow (cannula), and respiratory effort using Respiratory Inductive Plethysmography (RIP). Additionally, the AASM strongly recommends the use of another airflow sensor (thermistor) for oral breathing and apnea confirmation. CMS and many other insurance carriers have adopted these guidelines as the basis for HST reimbursement. Therefore, fulfilling these recommendations is important for proper medical evaluation as well as to meet many insurance requirements.

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Although business models and care pathways that can best utilize HST remain in flux, its adoption is growing and is expected to involve multiple stakeholders such as family physicians and their staff, sleep specialists, and others. Therefore, technologies that offer ease-of-use, high data quality, combined with efficient workflow will become critical in the near future.

Methods:

The technology consists of two components: a web portal (SleepView.com), and a wearable patient monitor (SleepView™). The webportal **(Figure 1)** is a cloud-based data management software that streamlines the various operations of HST including scheduling, device data upload, study archival, upload of additional data such as morning questionnaires, scoring and interpretation all via the internet. To further streamline the workflow, the webportal sends email notifications to users alerting them of study progress status. For example, once the study has been uploaded, a notification is sent to the assigned scorer for action, and once scoring is completed a similar notification is sent to the interpreting physician. Therefore, by internet-enabling the workflow, access to HST data by qualified resources is improved allowing fast and efficient turnaround of results.

Figure 1. Illustration of the Webportal, which allows an internet- based HST workflow.

The other component of the system is SleepView **(Figure 2),** which measures pulse oximetry, chest effort (respiratory inductive plethysmography), airflow (pressure), airflow (thermistor), body position, snore, and heart rate. The patient wears the following external sensors: a finger pulse oximeter, cannula, thermistor, and a respiratory *inductance plethysmography* effort belt (the belt is already connected to the SleepView). The other signals do not require external sensors; snore is derived from Figure 2. Home Sleep Monitor (SleepView). The cannula signal, heart rate is measured from the pulse oximeter and body position is determined from an internal 3-axis accelerometer.

The accelerometer sensor and associated circuitry were designed to be of high sensitivity and fast sampling rate for the purpose of detecting slight chest movements that could help differentiate wake from sleep states. A Rules Based Algorithm (RBA) was developed to derive sleep time by analyzing various parameters such as actigraphy and respiratory activity. Therefore, the algorithm is comprised of both actigraphy and respiratory analysis. First, the algorithm determines movement periods through feature extraction of 3-axis acceleration data taken from the SleepView device. These periods of movement are trended over the course of the study and the baseline sleep/wake hypnogram is determined through preset thresholds of that trend. Second, the algorithm determines sleep/wake epochs based on respiratory activity. Epochs in the baseline hypnogram where there are respiratory events and desaturations are then re-marked as sleep. Total Sleep Time (TST-PM) was estimated by subtracting the "Wake States" from Total Recording Time (TRT).

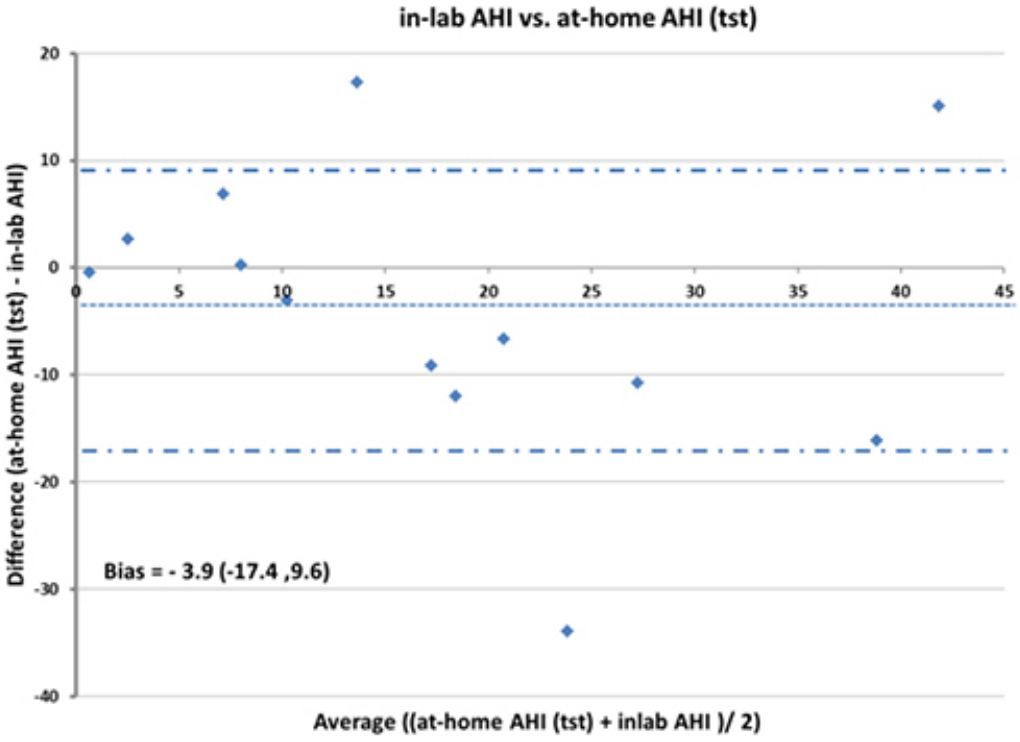
To facilitate sensor placement, light indicators are used to check for proper sensor attachment. Improper sensor connection will light up the respective indicator alerting the patient to adjust the sensor.

Clinical Protocol - 13 patients admitted for PSG at the Cleveland Clinic sleep center were recruited for the study. The morning following the PSG study, the patient was instructed by Cleveland Clinic staff on device use and sent home with the SleepView monitor. A system use instruction sheet was also provided. After the home study, the device was returned in a self-addressed package with a completed questionnaire regarding system's ease of use. Data was uploaded to the webportal, and run through the automated algorithm (respiratory event

detection and total sleep time estimation). The data was then manually over-read by a registered sleep technologist and report generated. The in-lab PSG studies followed the guidelines implemented at the

Figure 3. Bland-Altman analysis showing that AHI (TST) closely approximated in lab results (bias is –3.9 ± 13.5).

Cleveland Clinic with data manually scored by a registered sleep technologist without any automated scoring and over read by a sleep physician. Two separate technologists read the HST and in-lab studies.



Results:

The patient demographics are shown in **Table 1**.
Table 1. Demographics and summary statistics for 13 patients

Variable	**Mean ± SD**
Age (yr.)	48.7 ± 15.4
BMI (kg/m2)	31.5 ± 6.8
Men (n)	8
Female (n)	5
AHI	15.9 ± 12.9
ESS	11.7 ± 4.6

Patients were able to self-administer the study in the home with great success with the vast majority of patients rating usability between good and excellent (**Table 2**).

Table 2	**Number of responses (data available from 10 patients)**				
	Very poor	Poor	Acceptable	Good	Excellent
How easy was it to apply the SleepView sensors?	0	0	2	4	4
How well did the sensors stay on during the night?	0	0	1	5	4
My experience of the overall use of the SleepView was….	0	0	0	6	4

When compared to in-lab AHI, the web-based solution showed sensitivity of 100% and specificity of 67% (**Table 3**, AHI=5 was used as cutoff). These results were identical whether the at-home AHI calculation used TRT or TST in the denominator, which suggests no impact of study duration on disease *detection*.

Table 3. Sensitivity and Specificity analysis. In lab AHI vs. At home AHI (TST)

	In Lab AHI		
At Home AHI (TST)		Positive	Negative
	Positive	10	1
	Negative	0	2

Nevertheless, Bland-Altman analysis showed that the at home AHI calculations that used TST (AHI (TST)) were significantly closer to in-lab AHI's than at home AHI calculations that used TRT (AHI (TRT)). AHI (TST) exhibited a negative bias from in-lab AHI of 3.9 (**Figure 3**), while AHI (TRT) had a significantly worse bias of 5.6 ($p < 0.01$). Therefore, although both at home results under-reported the disease, the accuracy of home AHI calculations when compared to in lab studies significantly improved when TST was used.

Discussion:

A web-based data management and scoring service that utilized a HST monitor with manual over-read capability was developed and tested in the home successfully with high sensitivity and specificity to in-lab results. The finding that in-home testing was highly accurate in ruling-in the disease when compared to in-lab PSG is expected for monitors that utilize channel set and manual scoring methodology that are similar to that recommended by AASM. What is more revealing in the results is the confirmation that other human factors that could influence home recordings such as sensor hookup have not compromised the fidelity of the recordings suggesting monitor's simple operation and ease of use in the home. This finding was further supported by patient questionnaires.

The study found that AHI (TST) and AHI (TRT) generated identical sensitivity and specificity when compared to in lab results (i.e. disease *detection* with both methods was identical). However, AHI (TST) calculations yielded closer results to in lab AHI suggesting a better approximation of disease *severity*. The marked improvement in AHI (TST) is partly attributed to the underlying sleep state detection algorithm used in the home monitor. Unlike other methodologies that rely solely on actigraphy to derive sleep time, the algorithm relies on more comprehensive sleep-wake information, which merges chest actigraphy

with respiratory event detection data. The small sample size makes it difficult to derive conclusions regarding the ultimate clinical benefit of TST in home sleep evaluation. However, this research suggests a potential role in long-term disease management, which benefits from tools with more accurate tracking of disease severity.

This research supports the use of a new simplified and effective web-based methodology for sleep apnea evaluation in the home. We believe that the successful adoption of HST will require three core competencies: 1) reliable and easy to use home technology that avoids duplicative and costly in-lab confirmation, 2) improved care coordination through streamlined workflow among various stakeholders such as sleep physicians, primary care providers and other non-sleep specialists, and administrators, and 3) a continued central role of sleep specialists in supervising and managing the disease. Methodologies that meet these criteria will best serve patients, providers, and payers alike.

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