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Web-Based Data Management and Monitoring System for Sleep Apnea Evaluation in the Home

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Abstract

Study Objective: to assess the feasibility and accuracy of a web-based home sleep testing (HST) system for sleep apnea evaluation in the home.

Introduction: Sleep Disordered Breathing (SDB) affects more than 40 million patients with serious health and economic costs. Overcrowded sleep labs, patient resistance to sleep outside of their homes, and long-term disease management emphasize the need for a simple and cost effective solution for home sleep assessment.

Methods: The technology consists of a web portal (e-Crystal PSG) that allows users such as administrators, registered technologists and interpreting physicians to schedule studies, upload monitor data from any PC, and access raw data for scoring and interpretation irrespective of their physical location. Workflow is further streamlined via email notifications alerting users of the various stages of study progress: scheduled, device programmed, data uploaded, scored, interpreted, and finalized. The web portal interfaces to a seven (7) channel HST monitor (SleepView) that follows AASM channel set guidelines. To assess feasibility, the system was tested on 6 patients at a local sleep center; each patient underwent two (2) studies: in-lab full PSG on the first night followed by at-home SleepView study. The following day, the patient returned the equipment. Data from the SleepView and morning questionnaire were uploaded to the web portal, scored by a Registered Polysomnographic Technologist (RPSGT), interpreted and electronically signed by a sleep physician.

Results: All 6 studies generated high fidelity recordings with no loss of data or replacement to the sensors. All patients were able to hook themselves up, successfully. The ability to detect Obstructive Sleep Apnea (OSA) via SleepView matched in-lab PSG studies (Cutoff, AHI>5). To assess disease severity (normal, mild/moderate, severe), both in-lab and at-home studies showed identical evaluations except for one patient who was diagnosed as severe in the lab (AHI=44) and mild/moderate in the home (AHI=20).

Conclusions: a new web-based study management solution that permits streamlined expansion of HST was developed and tested successfully. Data from the SleepView monitor was of high quality when compared to in-lab PSG, and its ease-of-use facilitated self-administration in the home. The flexibility of the system may be particularly suited for HST deployment in large geographical areas where a streamlined process is required.

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Introduction

Obstructive Sleep Apnea (OSA) occurs when the upper airway collapses during the night, which fragments sleep and leads to excessive daytime sleepiness. The mechanism for airway occlusions is not yet fully understood; however, it is widely accepted that reduced neck muscle tone combined with abnormal pharyngeal anatomy and excessive fat tissue make the airways vulnerable to collapse during negative inspiratory drive. 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 total cessation of airflow for at least ten seconds, while hypopnea is defined as a drop of 30% or more in airflow or thoracoabdominal effort for at least ten seconds combined with oxygen desaturations of 4% or more. Therefore, the proper calculation of AHI requires the measurement of multiple parameters: airflow, respiration effort, and saturation level.

Home Sleep Testing per AASM Guidelines

A task force assigned by AASM concluded that home sleep testing can indeed facilitate and improve patient care provided that HST is done properly, which includes the acquisition of the appropriate type of physiological signals. The parameters recommended by the task force are: pulse oximetry, heart rate, airflow (cannula), and respiratory effort using Respiratory

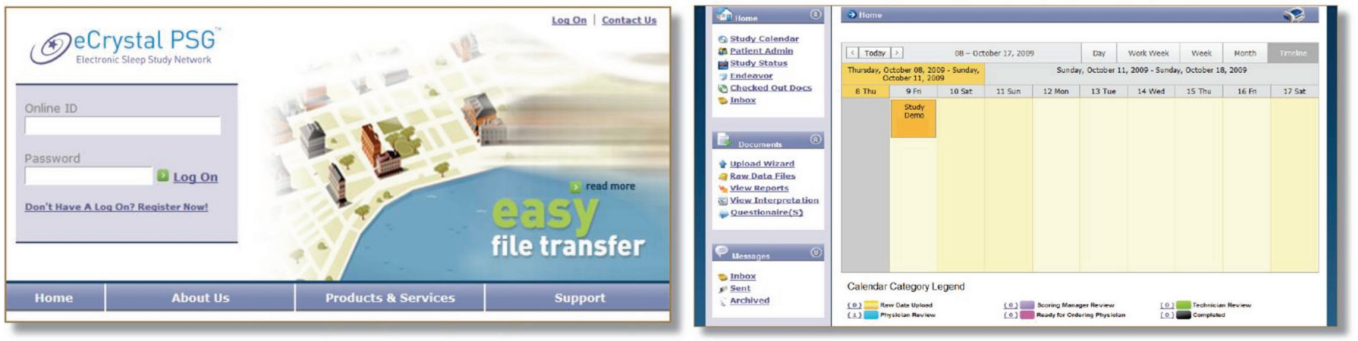

Fig. 1. Screen shots of the web portal (e-Crystal PSG), which is a sleep study management software that facilitates many aspects of HST deployment.

Inductive Plethysmography (RIP). Additionally, the AASM strongly recommends the use of another airflow sensor (thermistor) for oral breathing and apnea confirmation. Due to the complexity of the disease, the AASM guideline also requires qualified interpretation of the HST study by a sleep physician. These guidelines have been adopted as the basis for HST reimbursement by the Center for Medicare and Medicaid Services (CMS) and many other insurance carriers. Therefore, fulfilling these recommendations is important for proper medical evaluation as well as to meet many insurance requirements.

Although business models and care pathways that can best utilize HST remain in flux, the adoption of HST is expected to dramatically expand in the US. Therefore, technologies that offer high quality information combined with efficient workflow for patients, providers and payers, especially on a large scale, will be needed in the future.

Methods

The new technology consists of two components (manufactured by CleveMed): a web portal (e-Crystal PSG), and a wearable patient monitor (SleepView). E-Crystal PSG (Figure 1) is a web-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, e-Crystal PSG 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.

By internet-enabling the entire operation, the system opens up HST usage to more qualified resources allowing them to conduct various aspects of the workflow at different times and from various locations, thus improving overall efficiency. This can be useful for HST deployment for wide area coverage. For instance, national or even regional implementation by a healthcare provider may require study scheduling to happen in an administration center, device preparation and data upload by a nurse at a practice close to the patient (like a Primary care Physician Practice), scoring by RPSGT in a sleep laboratory, and interpretation by a sleep physician in his/her clinic.

The other component of the system is SleepView (Figure 2), which measures 7 parameters: pulse ox, chest effort (respiratory inductive plethysmography), airflow (pressure), airflow (thermistor), body position, snore, and heart rate. The patient hooks themselves up with the pulse ox, cannula, thermistor, and wraps the belt around their chest (the belt is already connected to the SleepView). The remaining signals are measured internally (do not require external sensors): body position measured by an accelerometer, snore is derived from airflow pressure, and heart rate is measured from pulse oximetry. Light indicators check the proper sensor attachment. Improper sensor connection will light up the respective indicator alerting the patient to adjust the sensor. The unit was pre-programmed to be turned on and off based on the patient's typical sleep schedule.

More extensive testing of the system that covers many sites will be done at a later date; however, in order to gain early feedback and assess feasibility and accuracy, the system was tested in a community based sleep laboratory environment.

Clinical Protocol - 6 patients diagnosed with OSA at West Region Sleep Center were recruited for next night at-home testing. After describing the study and obtaining consent, the patient was instructed on device use and given the SleepView monitor including a hookup instructions sheet. Next day, the patient returned the equipment to the sleep lab with a completed questionnaire regarding system's ease-of-use. Data were uploaded to the web portal, and scored by the same registered sleep technologists who scored the in-lab PSG's. All studies (6) were interpreted by the same board-certified sleep physician.

Results

The web portal was found to be very useful by the technologist and interpreting physician. Some recommendations to improve the workflow were made including expanding email notifications and availing the sleep report to the ordering physician.

2 of 6 patients were male (33%). Age ranged from 26 to 55 years old (average was 43 years old). All recordings (6/6) were

Fig. 2. Above - SleepView patient unit. Below - SleepView worn by a patient illustrating the hookup.

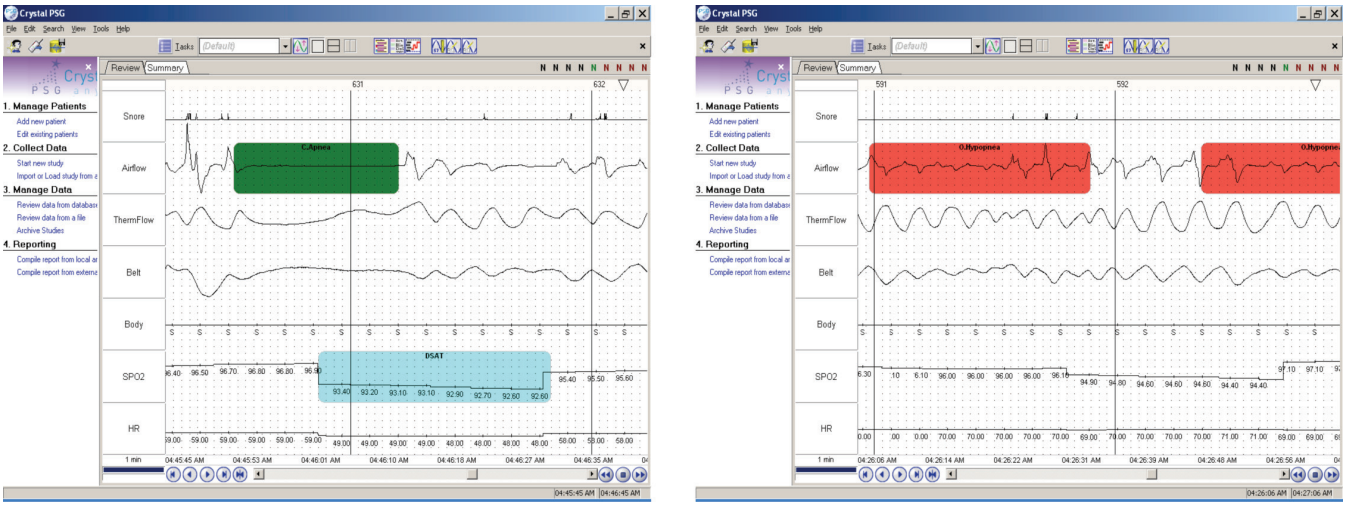

Fig. 3. Home sleep recordings using SleepView showing central apnea (left) and obstructive hypopnea (right).

completed successfully; no sensors fell off or needed replacement. All patients were able to hook themselves up using the attached instructions and a brief training in the sleep lab.

A typical recording is shown in Figure 3, which displays episodes of obstructive hypopnea, and central apnea. The at-home system showed an identical ability to detect the disease when compared to the lab studies using a cutoff AHI ≥ 5 (sensitivity of 100% and specificity of 100%). To assess disease severity (normal < 5, 5 ≤ mild/moderate < 30, severe ≥ 30), both in-lab and at-home studies showed identical evaluations except for one patient who was diagnosed as severe in the lab (AHI=44) and mild/moderate in the home (AHI 20).

	In-Lab	*At-Home*
Normal (<5)	2	2
Mild / Moderate (≥5, <30)	3	4
Severe (≥ 30)	1	0
Total	6	6

Discussion

A web-based data management software that interfaced to a 7 channel HST monitor was developed and tested in an in-lab environment successfully. More extensive research that tests the system in a national HST deployment is underway elsewhere. In this study, the software was used to facilitate HST evaluation of the SleepView monitor and to provide early feedback about the feasibility and functionality as viewed by a community-based sleep laboratory. The web-based operation functioned as expected and was able to conduct the necessary evaluation.

The finding that in-home studies generated very high accuracy in detecting the presence of OSA when compared to in-lab PSG is not surprising because the SleepView monitor utilizes a channel set and measurement methodology that is identical to that used in sleep laboratories, which is a channel set that is also recommended by the AASM. What is more revealing behind at-home and in-lab comparisons, however, relates to other factors that may influence signal quality, particularly the sensor hookup. The high accuracy of this study confirms the reliability of the sensor hookup process in Sleep View and the simplicity of its self-administered nature. Finally, disease severity findings showed one in six home recordings with lower severity than the in-lab diagnosis. This is not surprising as underestimation of disease severity is typical in HST because RDI is calculated based on total recording time, not total sleep time, which lowers the overall index.

This research, while preliminary, supports the use of a new simplified and effective home technology for sleep apnea evaluation. We believe the future expansion of HST will require three core competences: 1) reliable and easy to use home technology that avoids duplicative and costly in-lab confirmation, 2) improved workflow efficiency among the various stakeholders that are expected to participate in HST such as national sleep management companies, out-of-center operations and other healthcare providers, and 3) a continued central role of the sleep physician in supervising and managing the disease. The SleepView / e-Crystal PSG system provides the necessary infrastructure for these core competencies.

Acknowledgements

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Literature Cited

1. Wake up America: A National Sleep Alert. Report of the National Commission on Sleep Disorders Research, 1993
2. Frost and Sullivan Marketing Report, 2001, A071–56
3. Feedback Research Services, Sleep Screening and Testing Markets, Marketing report, August 2001
4. Kryger, "Principles and Practice of Sleep Medicine", Third Edition, Saunders, 2000
5. Dyken et. al., "Investigating the relationship between stroke and sleep apnea", Stroke 1996;27: 401–407