

Remotely Attended Home Monitoring of Sleep Disorders

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Abstract

This research assessed the feasibility of home monitoring of sleep disorders using small wireless technologies. There are many different types of sleep disorders that affect over 40 million patients. Sleep diagnosis is typically done in a laboratory where patients are asked to stay overnight, during which time various types of physiological signals are recorded. A more attractive alternative to in-lab testing is to evaluate patients in their own homes. In addition to convenience, the home environment is more conducive for natural sleep, which allows a true capture of disease symptoms. We describe a new easily deployable home monitor that will permit complete sleep evaluation in the patients' homes under direct remote supervision of a sleep specialist. The new technology, PSG@Home, consists of a 14-channel wearable wireless monitor and a cell phone-based Gateway to transfer data, including video, in real-time from the patient's home to a remote laboratory. Similar to in-lab recordings, data can be monitored and scored in real-time. The technology was tested on 10 fibromyalgia (FM) patients, whose constant pain has previously made them reluctant to travel to a sleep lab. All 10 studies were successful and generated high-fidelity recordings. One study experienced intermittent real-time data transmission due to sparse cellular coverage, but the data were recovered from a backup memory housed inside the patient monitor. No disconnections in sensor lead wires occurred. A new enabling home telehealth technology for real-time sleep disorders monitoring was developed and tested with encouraging preliminary results. The sample size is too small to derive any clinical conclusions about the sleep quality of FM patients. However, this study validates the underlying technology and demonstrates the role of new wireless technologies in the future of sleep disorders diagnosis.

Introduction

A report by the National Commission on Sleep Disorders Research indicates that 40 million Americans suffer from chronic sleep disorders, with 12–20 million Americans suffering from obstructive sleep apnea (OSA).¹ More than 200,000 automobile crashes per year may be sleep-related with one third of fatal trucking accidents due to fatigue. The cost impact is also staggering. For instance, the estimated direct annual cost for OSA is estimated at \$16 billion.^{2,3}

Sleep disorders are diagnosed during an overnight stay in a sleep laboratory where patients are asked to undergo a polysomnography (PSG) study. During a PSG study, the patients are hooked up with many electrodes and sensors that collect a number of physiological signals including brain and heart signals, leg motion, respiration, blood oxygenation, eye motion, and others. The patient's data are continuously monitored during the night for abnormal activities such as breathing disturbance, fragmentation of sleep state, seizures, or leg twitching. In addition, real-time video of the patient's sleep is also included to monitor any unusual behavior such as nightmares, sleep-walking, and others. Some forms of sleep disorders, like sleep apnea, require an additional overnight stay in the lab to initiate treatment (continuous positive airway pressure).

A more convenient approach is to conduct sleep testing in the patient's home. Although home sleep monitoring has been attempted before, the results generated little enthusiasm among the sleep community, mostly because of the low fidelity of the recording. Four published studies that compared multichannel home monitoring, which were conducted in an unattended fashion, to facility-based PSG showed highly variable and often low specificity for a correct diagnosis of sleep apnea. The data showed varying degrees of false-positive results that ranged as high as 31% of those testing positive.⁴

One of the main reasons for the inaccurate recording is due to sensor disconnections during the night as patients toss and turn. Because all home sleep recordings thus far have been conducted

without any supervision, as an “unattended study,” the doctor or sleep technologist never had the ability to alert the patient or their partner to intervene should the need arise, for instance, to instruct to adjust a sensor when it becomes loose. Another hurdle to home sleep monitoring is the size and overall complexity of the monitoring system itself. In order to provide diagnostic information (not just disease screening), many channels of physiological information are needed, which make the monitoring system large, not wearable, and not easily operated by patients in the home. Because they are not wearable, devices for home diagnosis are typically placed on a nightstand, making an already vulnerable sensor connection even more prone to detachments.

In this paper, we propose a new compact telemetry-based sleep monitor that is very easy to transport, wear, and offers reliable recordings. Furthermore, the system, which we call PSG@Home, can transmit data including video in real time to a sleep technologist, which offers valuable information in diagnosing difficult behavior-related disease states such as parasomnias. Also, video monitoring can often confirm sensor detachments; thus affording the technologist the ability to intervene should the need arise by phoning the spouse to adjust a sensor when needed.

As mentioned before, there are many types of patient populations who can benefit from home sleep diagnosis. One patient group that was selected for this research is the fibromyalgia (FM) population, who represent an underserved population and whose chronic pain has often made them resist traveling to a sleep lab. FM exists in 0.5% of men and 3.4% of women in the United States, with sleep disturbance affecting 76–90% of the patients compared with 10–30% in normal subjects.^{5,6}

Methods

Home telehealth offers a compelling alternative to the traditional method of in-lab sleep disorders evaluation, especially for those patients who cannot or are unwilling to travel to a sleep lab. CleveMed has developed a wireless PSG system (Crystal Monitor 20 Series, Cleveland, OH) that can be worn by the patient (*Fig. 1*, right). The monitor transmits up to 14 channels of PSG data wirelessly to a PC located up to 100 feet away. Therefore, cumbersome cabling between the patient and the PC is eliminated, thus facilitating home use including getting to bed and starting the study. The Crystal Monitor 20 served as a great platform but was not designed to transmit data over many miles, which would be needed for any home monitoring application. Therefore, in order to extend data transmission, we incorporated cell phone capability in a gateway and optimized the data communication protocols.

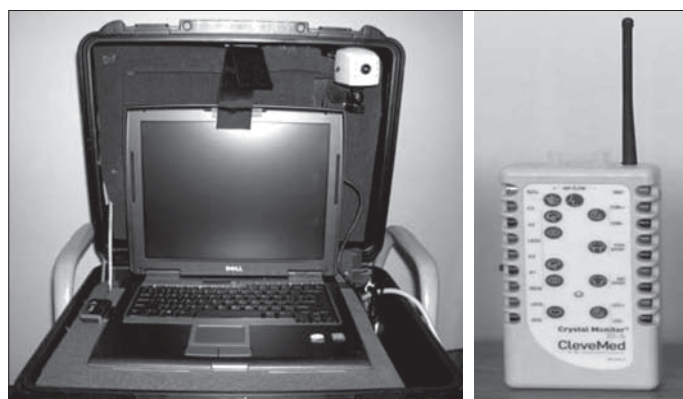


Fig. 1. The PSG@Home system. **Left:** Gateway. The case shows the laptop, camera, and cell phone connection (left side of the laptop). The Receiver is a separate unit attached to the back of the display (not shown). Internal Bluetooth receivers, often included in many laptops, can also be used instead of a dedicated external Bluetooth receiver. **Right:** The wearable transmitter, which connects to sensors and electrodes. PSG data are transmitted from the wearable transmitter to the Gateway, which in turn relays it over cell phone to a remote server where the sleep technologists can view and score the data.

PSG@HOME EQUIPMENT

The equipment consists of a wearable transmitter and a Gateway case (*Fig. 1*).

WEARABLE TRANSMITTER

The transmitter is a small battery-powered monitor that measures 5 inch × 2.5 inch × 1.1 inch, weighs less than 210 g and can be clipped on the patient’s thoracic respiration effort belt. The device can record and transmit up to 14 PSG channels: C3-A2, O2-A1, LOC-A2, ROC-A1, chest respiration effort, abdominal respiration effort, pulse oximetry, airflow, snore, body position, electrocardiogram, leg electrocardiogram (EMG), and DC auxiliary. The DC auxiliary channel was not used in this study. The transmitter amplified and filtered the signals and wirelessly transmitted the data over Bluetooth or 900 MHz band to the Gateway (described below). The transmitter simultaneously stores the data on an SD card housed inside the transmitter, which serves as a data backup should the radiofrequency (RF) link to the Gateway become interrupted.

GATEWAY

The Gateway, housed in a briefcase, consists of a small RF receiver connected to the back of a laptop via USB. The receiver demodulates the PSG data transmitted by the wearable unit and forwards it to the

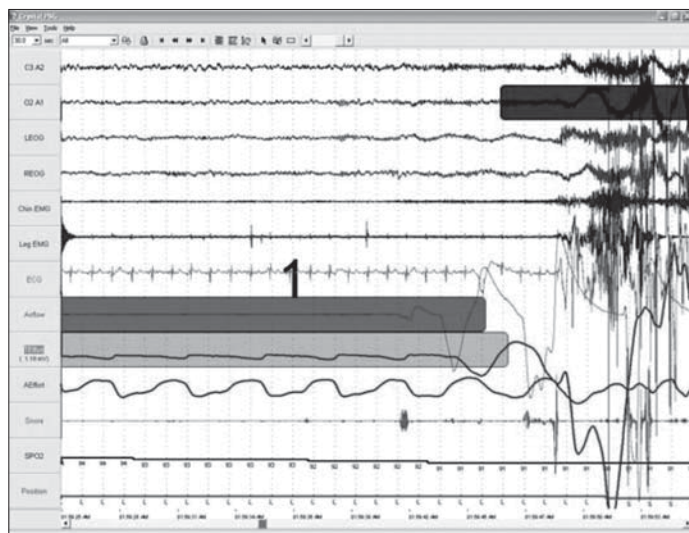
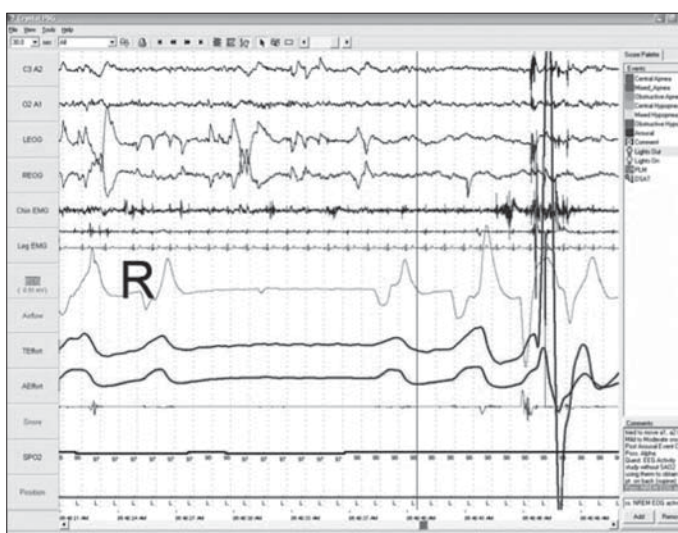
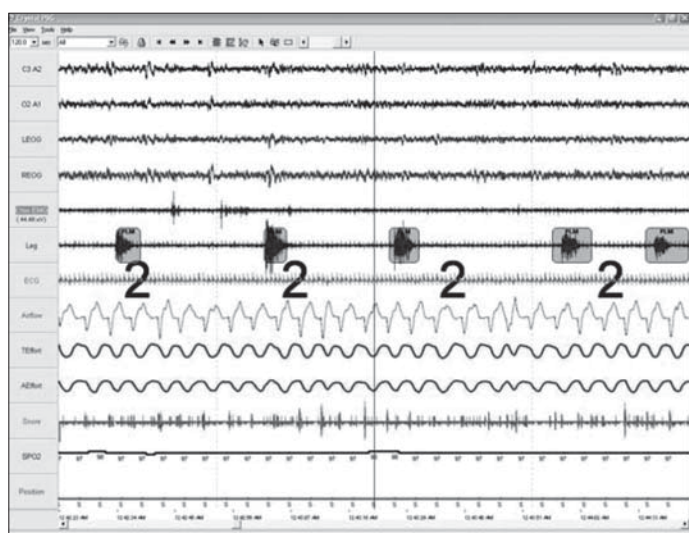


Fig. 2. Three recordings taken from two fibromyalgia (FM) patients illustrating various sleep disorders. **Upper left:** Patient 1. Periodic limb movement disorder. **Upper right:** Patient 1. Central apnea activity during REM. **Left:** Patient 2. Obstructive sleep apnea. These recordings demonstrate the feasibility of PSG@Home recordings taken in real time from the patients' homes, thus offering a unique ability to investigate diagnostic and treatment options for patients from the comfort of their homes.

laptop, which in turn saves it to the hard drive and displays it on the screen. The laptop has an internal cell phone card that connects it to a remote server location. The briefcase also has an infrared video camera that protrudes once the briefcase is opened, thus offering real-time patient visualization throughout the night (similar to in-lab operation). The infrared camera was connected to the laptop via a USB.

PATIENT HOOKUP

Ten ($n = 10$) patients, recruited by a local clinic, were tested. The patients came to the attending physician's office and were hooked up

with electrodes and sensors similar to the hookup applied during standard in-lab testing. The wearable transmitter was placed on their thoracic belt. Once hookup is completed and signals verified, the patient was sent home with the PSG@Home briefcase. At home and before going to bed, the patient places the Gateway on a nightstand facing the bed, opens the case and presses the power button, and then calls the sleep technologist to inform them that they are ready to go to bed. The sleep technologist logs onto a secured server, and runs a remote desktop program (VNC), which allows him/her to view the data and video in realtime. If any of the data or video camera needed adjustments, then the technologists would call the patient back for intervention. The technologists could also simultaneously score the data during the night, which improves study productivity. In the morning, the patient would disconnect the sensors with warm water and return to the doctor's office to deliver the equipment and review his/her results.

Results

Our results showed that all data from all 10 patients were scorable with no loss of electrode connections whatsoever. A brief phone call

before the patient went to bed was often made to correct the camera position (future design will eliminate this step by including a camera that is remotely controlled by the technologist). The Gateway package was a little bulky, but was manageable by all patients. Transmission delays due to cell phone connectivity was 2 seconds on average. In 1 out of 10 patients (10%), data transmission was slow due to sparse cell phone coverage in the patient's home area. One (1) of 10 studies (10%) required airflow sensor adjustment in the middle of the night (cannula shifted out of position). In that case, the sleep technologist called the patient during the night to correct. A board-certified sleep technologist scored all recordings in real-time, except for the one recording that had sparse cell coverage, which was scored the day after. All sleep parameters were collected including sleep staging, sleep time, and event scoring. Nocturnal video events were also acquired and stored within the PSG data file for later retrieval if needed. Clinical findings from these results will be summarized in a later publication. *Figure 2* shows typical recordings from two patients, which showed some notable sleep events. Feedback from the patients on the usability of the device and the overall benefit of the procedure was very encouraging.

Discussion

A system that can conduct sleep monitoring from the patients' homes was developed and preliminary testing was conducted. The system is portable and easy to operate by the patients. Preliminary data are encouraging as evidenced by no loss of recordings or sensor placement. All data were scorable and reports generated. The study required minimal intervention by the technologists and the results showed that patients would be accommodating to phone calls by the technologist to fix any sensor issue that might appear during the night. One (1) of 10 recordings had sparse cell phone coverage that prevented real-time monitoring, but the study was scored using backup memory. In contrast to the traditional unattended home sleep monitors, which cannot ensure signal fidelity, the PSG@Home sleep system offers attended monitoring capability, which allows higher-fidelity recording.

Future developments include a smaller Gateway package with embedded two-way phone communication and a video camera that can be remotely controlled by the technologist. The new camera will

also permit zooming capability, which offers more detailed confirmation of nocturnal events such as leg twitches and seizures, which further expands overall system capability. Follow-up articles will highlight the clinical findings from this study but this report offers a validation of the underlying technology and demonstrates the important role of wireless technologies in the future of sleep evaluation.

Acknowledgments

This development effort was funded by grants from the National Institutes of Health, National Institute of Neurological Disorders and Stroke (NINDS) and National Heart Lung and Blood Institute (NHLBI).

REFERENCES

1. Wake Up America: A National Sleep Alert. Report of the National Commission on Sleep Disorders Research, Washington D.C.: Health and Human Services, **1993**.
2. U.S. Sleep Apnea Diagnostics and Therapeutics Markets, Marketing report A071-56. Frost and Sullivan, **2001**.
3. Sleep Screening and Testing Markets, Marketing report. Feedback Research Services, August **2001**.
4. Chesson AL Jr, Berry RB, Pack A. Practice parameters for the use of portable monitoring devices in the investigation of suspected obstructive sleep apnea in adults. *Sleep* **2003**;26:907-913.
5. Yunus MB, Masi AT, Calabro JJ, Miller KA, Feigenbaum SI. Primary fibromyalgia (fibrosis): Clinical study of 50 patients with matched normal controls. *Arthritis Rheum* **1981**;11:151-172.
6. Schaefer KM. Sleep disturbance and fatigue in women with fibromyalgia and chronic fatigue syndrome. *J Obstet Gynecol Neonatal Nurs* **1995**;24:229-233.

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Received: July 6, 2007
 Accepted: July 23, 2007