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A NEW DEVICE FOR HOME SCREENING OF OBSTRUCTIVE SLEEP APNEA USING HOLTER OXIMETRY

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ABSTRACT

Purpose: This report describes the use of two new devices for screening of obstructive sleep apnea syndrome (OSAS). Holter apnea monitoring (continuous electrocardiogram recording) and Holter oximetry (continuous electrocardiogram recording and continuous pulse oximetry) were used on patients in the home setting to diagnose OSAS. We describe the reliability of these devices used in the unattended home environment.

Method: The Holter apnea monitor produces an apnea hypopnea index (AHI) based on an automated processing method of a continuous electrocardiogram with or without oximetry. Previous reports have shown that this method distinguishes normal from significant apnea recordings in 100% of cases. In the present study 64 patients were tested with one of the two devices. The reliability was determined by the number of tests completed without interruption due to electrode or device failure.

Results: Sixty (60) adults and four (4) children (ages thirteen and under) were tested. The Holter apnea monitor was used on 14 adult patients and the Holter oximeter on 47 adults and 3 children. Because this new OSAS screening device requires only the application of chest surface electrodes with or without a finger oximeter, patient acceptance was 100% and all had usable data.

Conclusion: A new, highly reliable, non-invasive diagnostic for obstructive sleep apnea (that can be used in adults and children) is reported. This technology appears to represent a major advance in unattended sleep apnea detection in the home. Its ease of use makes it one of the first objective home screening devices available for adults and children.

INTRODUCTION

Obstructive sleep apnea syndrome (OSAS) is common in the adult population, and though estimated at 4% of men and 2% of women, this figure likely underestimates its true incidence.[1,2] In children, published figures range from 1% to 3% and as in the adult population may underestimate the true prevalence due to a lack of formal testing in the pediatric age group.[3,4,5]

Polysomnography (PSG) has long been considered the gold standard for the diagnosis of OSAS, but its use is limited by the availability of sleep centers and the costs of the tests. Other screening tests have been proposed over the past twenty years ranging from simple overnight pulse oximetry to more complex multichannel home devices.[6] Previous studies have determined that single lead ECG recordings from sleep study patients can detect obstructive sleep apnea with great sensitivity and specificity in the laboratory setting .[7,8,9] The ideal screening test should be easy to use both by clinician and patient. It should be portable, inexpensive and reliable. It should, if possible, be adaptable to both adults and children.

Herein reported is a new device, recently developed, that uses data from Holter (continuous ambulatory ECG) analysis to determine an estimated apnea hypopnea index (AHI) and thus the existence and severity of OSAS. We tested this device in the unattended home setting and its reliability and patient acceptance is reported.

MATERIALS AND METHODS

Over a 10 month period from March 2006 to January 2007, a total of 64 patients presenting with clinical manifestation obstructive sleep apnea (in an otolaryngology practice), were offered a home sleep apnea screening test using the new screening devices. Fourteen patients were tested with the Del Mar Reynolds Lifescreen Apnea device (Del Mar Reynolds, Inc. 1 Ames Court, Plainview NY 11803 USA) and 46 patients were tested using the NEMON OxyHolter DR 180+ recorder (NorthEast Monitoring-NEMON, Maynard Mass, USA). There were 4 children (ages 6, 7, 11, 13) in this population. (Population Demographics are in table 1.) We did not intend to compare one device to the other. The Holter oximeter device became available during the testing period and represented in our opinion an improvement on the Holter only device, because of the benefit of simultaneous pulse oximetry data during the studies. The underlying technology is the same and described below.

Patients presented to the New York Otolaryngology Group (NYOG, New York, NY) at the end of the day and were fitted with the device by a medical assistant. Chest electrodes were placed on the patients and the finger oximetry probe was secured to the patients' index finger in the case of Holter oximetry patients. Patients (and children's parents) were instructed on the use of the device and were asked to remove the device the next morning and return it to the office.

Patients were instructed to record the time at which they went to sleep and the time at which they awoke and any other events during the night. They were also asked to fill out a brief questionnaire which inquired about any discomfort related to the device, either during the day or night. When the device was returned, the medical assistant obtained any other information regarding the test and inquired specifically about electrode disconnections during the test. Data was then transferred via a compact flash card from the Holter device to a desktop computer for analysis.

RESULTS

Holter Oximetry:
The combined electrocardiography (ECG) and oximetry system processed the ECG and/or oximetry signals and produced two outputs. The first output was an epoch-by-epoch sequence of annotations of "normal" or "SDB" (sleep disordered breathing). The second output provided an estimate of the apnea hypopnea index (AHI), derived from the epoch-by-epoch annotations. A pattern recognition approach using supervised learning was utilized, with classifier methods based on linear discriminant analysis applied to particular signal features. [10] Fundamentally, the system processes an epoch of data and allocates the epoch to either "normal" or "apnea".

For oximetry systems, previous studies have investigated time based features such as the percentage time below a certain level, the sum of the differences between successive readings (delta index), the number of dips in oxygen saturation per hour, and frequency based features such as the spectral peak in the SpO_2 spectrum and pulse rate periodogram in the range 30-70 seconds.[11,12,13]

The ECG is preprocessed using a bandpass filter (0.5-40Hz) to remove baseline wander and high frequency interference. A QRS peak detector is applied, capable of detecting over 99% of QRSs with a false detection

rate of less than 1%. RR intervals are defined as the interval between successive QRS detection points. Suspect RR-intervals were found by applying a 5 point median filter; automatic interpolation/deletion was performed.

An interval-based RR sequence (60 second epoch length) power spectral density (PSD) estimate was calculated. The sequence was zero-padded to length 256. Averaging of four adjacent frequency bins yielded a 64-point PSD estimate of which the first 32 points were used as features. The time domain features used were the first five serial correlation coefficients, transformed standard deviation of RR and delta RR (change in adjacent RR values), and the transformed mean epoch RR interval. [7, 8, 9]

During the breathing cycle, the body-surface ECG is influenced by electrode motion relative to the heart and by changes in thoracic electrical impedance as the lungs fill and empty with air. The effect is most obviously seen as a slow modulation of the ECG amplitude at the same frequency as the breathing cycle.[14] A double median filtering and integration process was used to isolate the estimated respiratory modulation of the ECG about the QRS complexes.[8] The EDR features used were based on PSD estimates, using 256 point zeros padding, averaging to 64 point, and using first 32 points.

SpO_2 preprocessing focused on removing obvious artifact. All changes of oxygen saturation between consecutive sampling intervals of greater than 4% per second were considered to be artifact, as were all SpO_2 values of less than 65% or greater than 100.1%. A 5-minute running average of the SpO_2 signal was generated. The original SpO_2 signal and estimated baseline version were then resampled to 0.1Hz. If no artifact was detected in the oximetry signal in an epoch then the following features were calculated: the mean and minimum SpO_2 values, a count of SpO_2 values of less than 92% saturation, a transformed 5% to 95% spread in sorted SpO_2 values, and the mean of the absolute differences between successive SpO_2 samples. In addition, the following two features were calculated using both the resampled SpO_2 and estimated SpO_2 baseline signals: a count of the number of times the SpO_2 and SpO_2 estimated baseline were within +2.9% or –2.9% of each other during each epoch.

An estimated AHI was derived by from the per-epoch classification by counting the average number of detected apnea segments per hour of sleep (based on information supplied by the patient) and automatically applying an appropriate threshold.

Patients: Sixty-four patients were evaluated and underwent sleep studies using the new technology. All were able to complete the study at home without interruption. There were 4 children tested: two 7-year-olds (one boy, one girl), an 11-year-old boy and a 13-year-old boy. In this group the AHI ranged from 1.0 to 15.9. The average BMI was 24.5 (range14.4-39.1). Testing was carried out in this group because of snoring, suspected sleep apnea and tonsillar hypertrophy. Among all patients tested there were 22 females and 42 males. The average age was 42 (range: 7-75). The average AHI was 16.6 (range: 1.0-106). Average BMI: 31 (range: 18.7-65.3). The prevalence of OSAS in this group based on AHI>5 was 39 of 64 patients or 61%. (Table 1.)

The sleep study data was usable in 100% (64/64) of patients. The algorithm evaluating the ECG and oximetry signal was able to compute the AHI in all patients, however oximetry data was absent in one patient. When oximetry disconnections occurred, the software was still able to calculate the AHI based on ECG signal alone although the clinician did not have all the oximetry information available.

We noted that oximetry data was completely absent in 1 patient. In 12% of cases oximetry data was absent greater than 50% of the study time, and in 27% of cases oximetry data was absent 20% of the study time. The absence of data was caused by movement artifact of the finger probe during sleep.

Patients were free to add comments on the questionnaire regarding their experience with the device. Three patients had written comments: One that the device was "awkward", one complained about chest electrodes discomfort, and one suspected more awakenings due to the device.

DISCUSSION

De Chazal and Heneghan have previously shown that their automated processing of the single lead ECG can separate normal from apneic recordings in 100% of adults tested for OSAS.[7] Their study compared the ECG recordings from a databank of patients with known obstructive sleep apnea syndrome to those of normal controls; the method also had a minute by minute accuracy of 90%. They concluded that this technology was comparable to full PSG for the diagnosis of OSA and they suggested its use as a screening tool.

A study by Shouldice et al. reported the accuracy of detection of OSAS in children using a similar method.[8] In that study they compared the accuracy of Holter sleep apnea detection with full PSG. The Holter apnea device correctly identified 12 of 14 patients with sleep apnea. The positive predictive value was 85.7% and the negative predictive value was 81.8%. The false negatives were for cases of mild OSAS (AHI: 2.6, 3.0 and 6.4) and one case of a morbidly obese child with a BMI of 51.8; the authors hypothesize that the known reduction in overall low-frequency heart rate variability in obese children could explain this result.

This paper is the first report of the use of the Holter oximeter in the unattended, home setting for the screening of OSAS in adults and children. Holter monitoring has a long clinical history and is known to be a well tolerated and reliable test. Holter oximetry for the detection of sleep apnea requires only the application of adhesive chest electrodes and the application of a finger probe oximeter. In our series, a medical assistant connected patients to the device although many patients could have performed this task on their own at home. Sleeping with the device caused only minor complaints in three patients, and all of these patients completed their sleep study. None of the patients complained of this test as an interference with their daily life, in fact most patients were surprised and pleased with the ease of use and rapid test results. Our experience with the fitting of the device on children was also positive and there was no data loss and no complaints in the small group of children tested.

The data reliability rate compares very favorably to other devices where 4-33% of data from home screening tests are lost.[15,16,17,18,19] We attribute the data reliability rate to the ease of application and wearing of the device as well as the robustness of the ECG signal. Even if the pulse oximetry sensor becomes displaced, the software can reliably calculate the AHI. In these cases the clinician will lack some of the oxygen saturation information. This may hinder clinical decision making in cases of borderline OSAS with AHI between 5 and 15. There was only one patient in our series of 64 in whom all pulse oximetry data was missing.

Other home screening devices have been developed over the years as an alternative to PSG. Methods have ranged from unattended home PSGs to simple pulse oximetry. Home PSGs are impractical, rarely available

and not likely to be cost effective. In one study 33% of unattended home PSGs were too unreliable and in 11% of cases had discordant results.[15] Simpler home screening devices are often less reliable but easier to use by patients.

We believe that the Holter oximeter represents a very promising new method of screening for OSAS in the unattended home environment. It is especially promising in the pediatric population where the most common screening device has been pulse oximetry alone.

Many studies have evaluated pulse oximetry alone as a measure of OSAS. This method has been used because of its ease of use, low cost and wide availability in the clinical setting. Despite conflicting results it has been suggested as a screening test in the pediatric population. The pathophysiology of OSAS in children is different than that in adults with frequent episodes of upper airway obstruction that are not associated with saturation drop.[20] Other problems with pulse oximetry in children are the large numbers of movement artifact due to generally more restless sleep of children.[21] These artifacts can cause low saturation recordings and a large number of false positive findings. A recent study altogether questions the validity of pulse oximetry in children and suggests that if used as a test for the diagnosis of OSAS it should be associated with additional sensors such as motion sensors or measures of airflow.[22]

Our study has confirmed that the weakest link in data collection in our system comes from the pulse oximeter finger probes. It was also a greater source of discomfort for patients. The Holter oximeter uses the oximetry information as an adjunct to the information of the ECG signal. Even a complete absence of the oximetry signal during a study will not invalidate the calculated AHI.

Much of the criticism of home screening tests is the unreliability of the data and the poor correlation with PSG. The purpose of this current study was to evaluate the practical utility of the Holter-oximeter and Holter technology in a clinical otolaryngology setting. For completeness, Figure 2 illustrates the correspondence between polysomnography AHI and Holter-oximeter AHI when both were collected simultaneously in a hospital-based sleep laboratory. It can be readily seen that there is a very high level of agreement between the approaches. Moreover, it should be noted that PSG also has limitations. The PSG is subject to technician interpretation and is subject to inter reader variability.[23] PSG is also limited by the un-natural sleeping environment and interference of sleep position by the numerous surface electrodes placed on the patients during testing. One can argue that PSG should not be used for screening for OSAS because of its high cost and limited availability, but rather reserved for patients who require further testing after an appropriate OSAS screen has been performed. Also patients suspected of sleep disorders other than obstructive sleep apnea should be evaluated by PSG rather than screening devices. This remains a decision to be made by the clinician evaluating the patient. Using PSG to screen for children is particularly problematic because of the difficulty in obtaining data from children in sleep labs and the very long wait to test children for OSAS. We believe that screening for OSAS with Holter oximetry in children may be particularly useful as the test is more reliable than oximetry alone and is very well tolerated by way of its simple form factor. We intend to test this device on a greater number of children as we report only a limited experience in this paper.

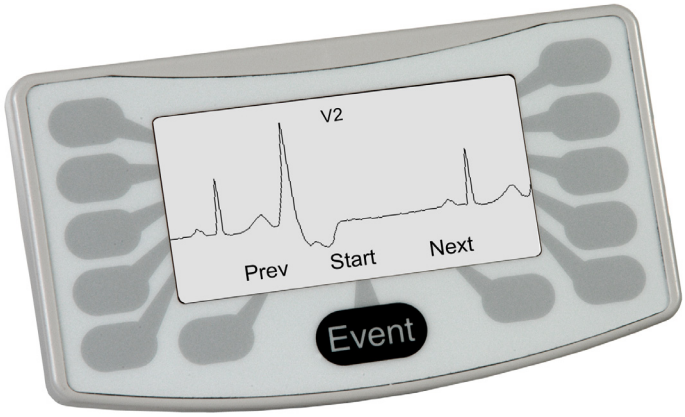
CONCLUSION

This report has described the clinical use of a new technology to diagnose obstructive sleep apnea in an unattended home setting. It uses time tested inexpensive devices (Holter and pulse oximetry) to produce a reliable and sensitive measure of the Apnea Hypopnea Index (AHI). Compared to other tests currently used for home screening of sleep apnea it has a very high reliability rate (100% in our series of 64 patients), and correlates very well with PSG. It should become a first line screening tool for OSAS in the adult population. As results of further testing on larger groups of children confirm our preliminary findings, it will very likely become a standard screening tool for OSAS in the pediatric population.

Table 1. Patient characteristics. N= 64

	Mean	Range
Age, years	42	7 - 75
BMI	31	18.7 - 65.3
Computed AHI	16.6	1.0 - 106

Figure 1. The Holter oximeter - The NorthEast Monitoring, DR180+ Digital OxyHolter Recorder



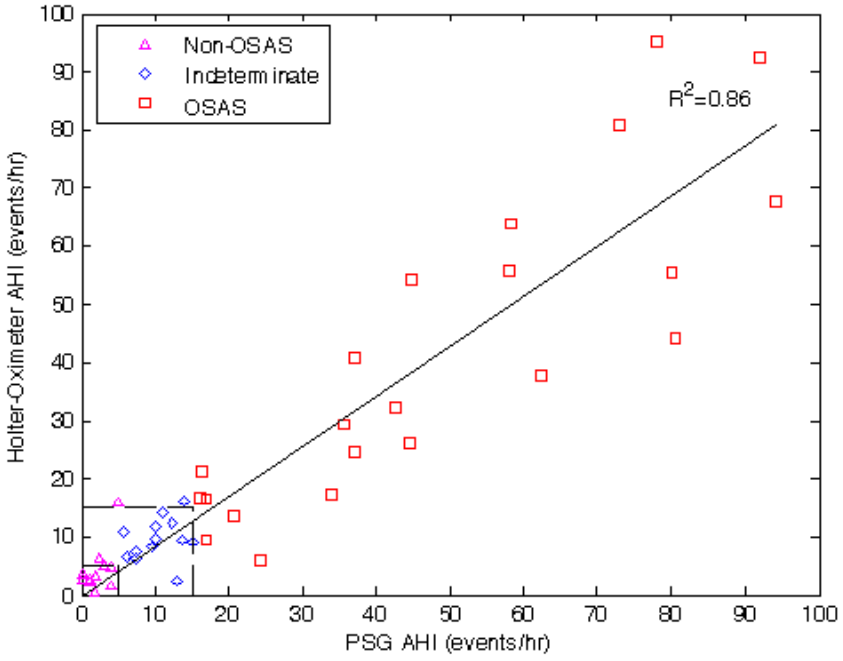


Figure 2.
Scatter plot of estimated and reference AHI.(PSG AHI) obtained in a companion study from 52 adult subjects (age ranges 50±10 (28 – 73) and BMIs 31 ± 6 (20 – 45)) The reference AHI was obtained from polysomnography. The estimated AHI was obtained from analyzing data recorded from the Holter-oximeter.

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