

## **RELIABILITY OF COMBINED HOLTER-OXIMETER FOR HOME SLEEP APNEA TESTING**

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## **ABSTRACT**

**OBJECTIVES:** To test the reliability of the combined Holter-Oximeter for home testing of obstructive sleep apnea. Previous reports have shown a 96% correlation between polysomnography and Holter-Oximeter in the sleep laboratory. This study was designed to measure the reliability of the Holter-Oximeter data obtained unattended at home as well as to obtain information from patients regarding acceptance of the device.

**METHOD:** Prospective study

**SUBJECTS AND METHODS.** One hundred and twenty consecutive patients (ages 5 to 81) presenting to an otolaryngology practice during a 4 month period with complaints of snoring or sleep apnea symptoms. Device: The combined Holter-Oximeter produces a sleep report including an apnea hypopnea index (AHI) based on an automated processing method from a continuous electrocardiogram and pulse oximeter. The reliability of the test was determined by the number of tests completed without interruption due to patient discomfort, electrode, or device failure.

**RESULTS:** Ninety seven percent (97%) of the tests administered provided usable data and a complete sleep report. In 4 patients, failure to generate a complete report was due to faulty memory cards in the device and or surface electrode failure. All patients tolerated wearing the device at home and there were no voluntary interruptions of the test by patients. On a discomfort scale of 0 to 10 (0: no interference with sleep and 10: maximal interference with sleep), the average discomfort score was 1.7. Seven patients

had experienced a PSG and their discomfort score average was 7.57 for PSG compared to 1.57 for the Holter-Oximeter test, ( $p < 0.0001$ ). Eight patients had at least 2 Holter-Oximeter tests during the 4 month testing period and no significant night to night variability was observed.

**CONCLUSIONS:** The combined Holter-Oximeter represents a new, easy to use, and reliable device for the home diagnosis of obstructive sleep apnea. It should be considered as an alternative to PSG in diagnostic testing for suspected obstructive sleep apnea. It can also be used to monitor the response to medical and surgical interventions for OSAS.

## 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<sup>1,2</sup>. In children, published figures range from 1% to 3% and as in the adult population may significantly underestimate the true prevalence of the condition due to lack of formal testing in the pediatric age group.<sup>3,4,5</sup>

Polysomnography (PSG) has long been considered the gold standard for the diagnosis of OSAS but its use has been limited by the availability of sleep centers and the costs of the tests. Home testing and screening devices have been introduced over the past 20 years with little success, due primarily to the unreliability in the unattended home environment.<sup>6</sup> The ideal home testing device for sleep apnea should be easy to use both by patient and clinician. It should also be portable, inexpensive, accurate, reliable, and if possible adaptable for use in adults and children. The combined Holter-Oximeter has been shown in previous studies to be as accurate as polysomnography.<sup>7,8,9,10</sup> It can be used in adults and children and is portable. This paper reports on the reliability of the Holter-Oximeter in the unattended home environment.

## **MATERIALS AND METHODS**

Over a four month period from October 2007 to February 2008, 120 consecutive patients seen in an otolaryngology practice were tested with the OxyHolter® DR 180+ recorder (North East Monitoring – NEMON – Maynard Mass, USA) . Approval from the local institutional review board was obtained for the protocol and informed consent was obtained on study participants. All patients who entered the study completed the home sleep testing and none were lost to follow up.

One hundred and twenty (120) patients were entered, 66% male, 34% female with an average age of 43 (range: 5 to 81). There were 5 pediatric subjects (ages 5, 6, 6, 7, 11). Average body mass index (BMI) for the study group was 32 (range: 19.5-72.9), see Table 1. Eight patients underwent multiple tests with the OxyHolter®; 4 patients had 3 studies, and 4 had 2 studies (Table 2). Four patients underwent PSG during a 10 year period preceding their OxyHolter® study. Comparative results are presented in Table 3. Three patients in the study also underwent a full PSG within 1 month of the OxyHolter® study, see Table 4.

Patients presented to the office the afternoon of the test and were fitted with the device by a medical assistant. Five adhesive chest electrodes and one adhesive pulse oximetry index probe were fitted and secured with additional tape. The device was removed in the morning by the patients in their home and brought back to the office for data download. A patient log including time of sleep and comments regarding any discomfort or electrode displacement was kept by the patient. A questionnaire was filled out by patients upon returning the equipment: it included scoring of the discomfort

produced by the device on a 10 point scale (0: normal sleep to 10: no sleep). Patients were also asked to rate any experience with a previous overnight PSG study if applicable using the same discomfort scale.

Data from the overnight tests were downloaded from the device onto a computer and an automated algorithm generated a full report including AHI, oximetry averages, and oximetry peak and nadir (see sample report summaries in Figure 1). The reports also specified the overall percent time during which there was an invalid reading from the pulse oximeter. This information helped the clinician determine the reliability of oximetry data. The device can reliably calculate the AHI even in the absence of the oximetry data.

**Holter-Oximeter.** The device used: OxyHolter® DR 180+ (North East Monitoring, Maynard, Mass) combines continuous electrocardiography (ECG) and a pulse oximetry system to produce a fully automated report including the apnea hypopnea index (AHI). See Figure 2.

The Holter-Oximeter analysis system has been described in detail in previous publications<sup>11</sup>. To summarize: the device has a one channel ECG input and a one channel oxygen saturation input. Two outputs are generated: the first is an epoch by epoch sequence (an epoch is a 30 second time interval of sleep), which is scored as “normal” or “apnea”. The second output is an estimate of the apnea hypopnea index (AHI), derived from the epoch by epoch annotations.

The system uses a pattern recognition algorithm that determines sleep disordered breathing based on the cyclical variations in heart rate associated with apnea, the ECG –

derived respiration, and changes in oxygen saturation<sup>12</sup>. Cyclic heart rate variations are analyzed using time and frequency-domain heart rate variability analysis of the RR interval time series. Respiratory effort is estimated by analyzing the magnitude of the QRS waveform. It is influenced by electrode motion relative to the heart and by changes in thoracic electrical impedance as the lungs fill and empty with air. Finally, apneic events are often associated with oxygen desaturations and these are detected by the pulse oximeter.

## RESULTS

We tested 120 patients using the Holter-Oximeter and generated 132 studies ( 8 patients had multiple studies generating an additional 12 studies). In 4 patients, the device did not generate a reliable report because of a malfunction which shortened the recording time. This accounted for a 3 % failure rate overall. Patients reported some discomfort associated with ECG leads and rolling over the small ECG recorder during sleep.

Most patients had positive studies with only 23 % having AHI scores below 5. Table 5 shows the distribution of AHI scores for patients tested with Holter-Oximetry.

The device automatically adjusts to “pediatric mode” (based on the date of birth entered) taking into account the different respiratory and cardiac patterns of children when calculating the AHI. In this study there were 5 children : all were able to complete the study without any difficulty.

Table 2 shows the AHI recorded by the Holter-Oximeter on different night-

recordings. The correlation coefficient between AHIs obtained on nights 1 and 2 is 0.98, indicating a high degree of test-retest reliability (this correlation coefficient is somewhat positively biased due to the presence of only one high AHI value in the analyzed data). As an alternative means of considering the data, one-way analysis of variance (ANOVA) shows that there is no statistically significant difference between Nights 1 and 2 ( $p=0.86$ ), meaning that the null hypothesis is accepted (i.e., the measured values are drawn from the same underlying observation). Finally, from an empirical clinical point of view, using the well accepted threshold of  $AHI>15$  as representing clinically significant apnea, none of the patients change their decision class as a result of repeating the test.

Test Discomfort: 72 of 120 patients answered the discomfort questionnaire (see Table 3). The average score was 1.77/10. Seven patients who had undergone PSG testing in the past also scored their experience using the same discomfort scale. The average discomfort was 7.57 – significantly more uncomfortable ( $p<0.0001$ ).

Only 3 patients in our series underwent PSG and Holter-Oximetry within a one month period. Despite this group of patients being very small, it is interesting to note the very similar AHI scores calculated by PSG and Holter-Oximeter. (see Table 4)

## DISCUSSION

Use of the continuous ECG recording as a test for detecting OSAS dates back to 1984 when Guilleminault (12) suggested that the cyclical variations in continuous night time ECG associated with sleep apnea could be used as a screening tool. Penzel et al in 2002 responded to the “apnea challenge” conducted by the IEEE’s Computers in Cardiology section and Physionet. (Physionet is a web based library of physiological data and analytical software sponsored by the National Institutes of Health’s Center for Research Resources (NIH NCR)). The challenge consisted of analyzing sets of ECG recordings from the Center’s database belonging to normal control patients and patients with OSAS. The results of the competition demonstrated that analysis of the overnight continuous ECG alone was able to correctly differentiate patients with OSAS from normal controls.<sup>13</sup>

This led to further study of the usefulness of overnight continuous ECG as a tool for the detection of OSAS. In 2004 De Chazal and Heneghan showed that their automated processing of the single lead continuous overnight ECG can separate normal from apneic recordings in 100% of adults tested for OSAS<sup>14</sup>. A study by Shouldice et al. reported the accuracy of the same testing technique in a pediatric population (8). The overnight continuous ECG 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 sleep apnea (AHI 2.6, 3.0, and 6.4) and in one case of a morbidly obese child with 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. More recently, the same group of authors produced results of prospective studies -- one on adults, another on children -- using the new Holter-Oximeter (adding the oximetry input in the data analysis) head to head against the PSG in a supervised laboratory environment. Comparing 56 adults who were tested simultaneously with Holter-Oximeter and PSG, there was a very high correlation between the AHI scores ( $r=.95$ ,  $p < 0.001$ ), and a sensitivity and specificity of 100% (10). In a similar prospective study on 50 pediatric subjects, the sensitivity of the Holter-Oximeter was 100%, and the specificity was 75%.<sup>15</sup>

Given the accuracy of the Holter-Oximeter compared head to head with PSG in the supervised laboratory setting (summarized in the preceding section), the goal of this study was to test the reliability of the device as a home test for sleep apnea in an unsupervised home environment. The 97% reliability rate (successful and usable tests completed without interruption), compares very favorably with other home sleep apnea testing devices where 4 to 33% of data from testing are lost<sup>16, 17, 18, 19, 20</sup>. We attribute the very high reliability of the Holter-Oximeter to the ease of use of the device both for the clinician and the patient, as well as the robustness of the signal (the ECG) used to capture data. Even if the pulse oximeter becomes temporarily dislodged during the testing, the software can reliably calculate the AHI based only on the ECG signal.

We had the opportunity to analyze test-retest results in a small subset of patients in our study who underwent 2 or 3 home tests within a 2 month period. We found no statistically significant difference in the AHI results on the different nights. These test-

retest results are similar to those from a study by Davidson et al.<sup>21</sup> The authors investigated the test-retest performance of a home based sleep study (the Embletta) and found no statistical difference in AHI between the first and second nights. This is in contrast to the results of Levendowski et al. who saw a statistically significant increase in AHI between night 1 and night 2 when using polysomnography<sup>22</sup>. We hypothesize that night-to-night variability is reduced in home sleep studies where a person is familiar with the environment, and has a reduced number of attached leads. The data from our sleep discomfort questionnaire supports this hypothesis as the average discomfort score was 1.7/10 in patients undergoing the home Holter-Oximeter test compared to a discomfort score of 7.57/10 for patients tested by PSG.

We only had a small number of children in our study but did not encounter any technical difficulties that interfered with the completion of the studies. Reliable home sleep studies in children are particularly challenging given the more restless sleep of children. Pulse oximetry alone has been used in children but a recent study questions its validity<sup>23</sup>. We intend to test a greater number of children to reproduce the reliability of the tests from our small pediatric study subgroup.

Some of the limitations of the Holter-Oximeter are its inability to currently differentiate central from obstructive apneic events. In addition, patients on beta blockers should if possible be taken off their medication for the duration of the test as beta blockers will interfere with the ECG variability associated with sleep apnea. Finally, other sleep disorders including restless leg syndrome and central apnea syndromes will

not be detected using the Holter-Oximeter.

Despite some of the above limitations, we believe the combined Holter-Oximeter may be a good alternative to PSG in patients requiring testing and especially repeated testing to rule out OSAS, and/or to document response to medical or surgical treatment for OSAS.

## **CONCLUSION**

This is the first published report of the reliability of the Holter-Oximeter as an ambulatory sleep testing device for the detection of sleep apnea in the unattended home environment. The device has proven very reliable with only 3% incomplete tests. Night to night variability in a small subgroup of patients was insignificant, and patients reported only minimal interference with sleep using the device at home. Given the ease of use of the device for both staff and patients (including children), it should be considered as an alternative to PSG and can be used to screen patients scheduled for upper airway or tonsil surgery. Further testing will be required in children to confirm the preliminary results in our small group of pediatric subjects.

## **AUTHOR INFORMATION**

Jordan C. Stern, MD is in private practice in New York and associate adjunct surgeon, Department of Otolaryngology, the New York Eye & Ear Infirmary. Conor Heneghan,

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### **AUTHOR CONTRIBUTIONS**

Jordan Stern, MD: study design, data collection and analysis, writer. Conor Heneghan, PhD: data analysis, writer. Redmond Shouldice PhD, data analysis, writer.

### **FINANCIAL DISCLOSURE**

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**Table 1. Study patient characteristics. N=120**

	Mean	Range	%
Age	43	5-81	
BMI	32	19.5-72.9	
Females	41		34%
Males	79		66%

**Table 2. Multiple night Holter-Oximeter tests, AHI scores.**

Patient	night 1	night 2	night 3
1	10.3	9.9	14.0
2	5.2	5.0	8.0
3	7.2	4.2	5.5
4	14.2	6.2	9.4
5	6.3	11.7	
6	3.3	2.3	
7	4.1	3.0	
8	73	65	

**Table 3. Comparison of discomfort score, PSG vs Holter-Oximeter.**

**Scale 0: normal sleep to 10 no sleep.**

Patient	Holter-Oximeter	PSG
1	3	9
2	0	8
3	1	10
4	0	7
5	2	7
6	1	5
7	4	7
mean	1.57	7.57

significant at  $p < 0.0001$

**Table 4.** Comparison of Holter-Oximeter AHI vs PSG AHI

Patient	Holter Oximeter	PSG
1	43.1	44
2	72.9	84
3	4	5

**Table 5.** Percentage of patients in the study with Holter-Oximeter AHI scores below 5, between 5 and 15, and above 15.

AHI < 5	>5 AHI < 15	AHI>15
23%	34%	43%



Estimated Apneic Epochs:	363	SpO2 below 90%:	21.4% of time analyzed	Invalid SpO2:	0.0% of total
Estimated AHI:	46.2	SpO2 below 85%:	8.0% of time analyzed	Highest SpO2:	96.4% of analyzed
#SpO2 desats $\geq$ 3% ( $\geq$ 10 sec):	159 [mean: 15.3 secs]	SpO2 below 80%:	2.3% of time analyzed	Mean SpO2:	90.6% of analyzed
#SpO2 desats $\geq$ 4% ( $\geq$ 10 sec):	94 [mean: 15.4 secs]	SpO2 below 70%:	0.0% of time analyzed	Lowest SpO2:	67.8% of analyzed

Comments:

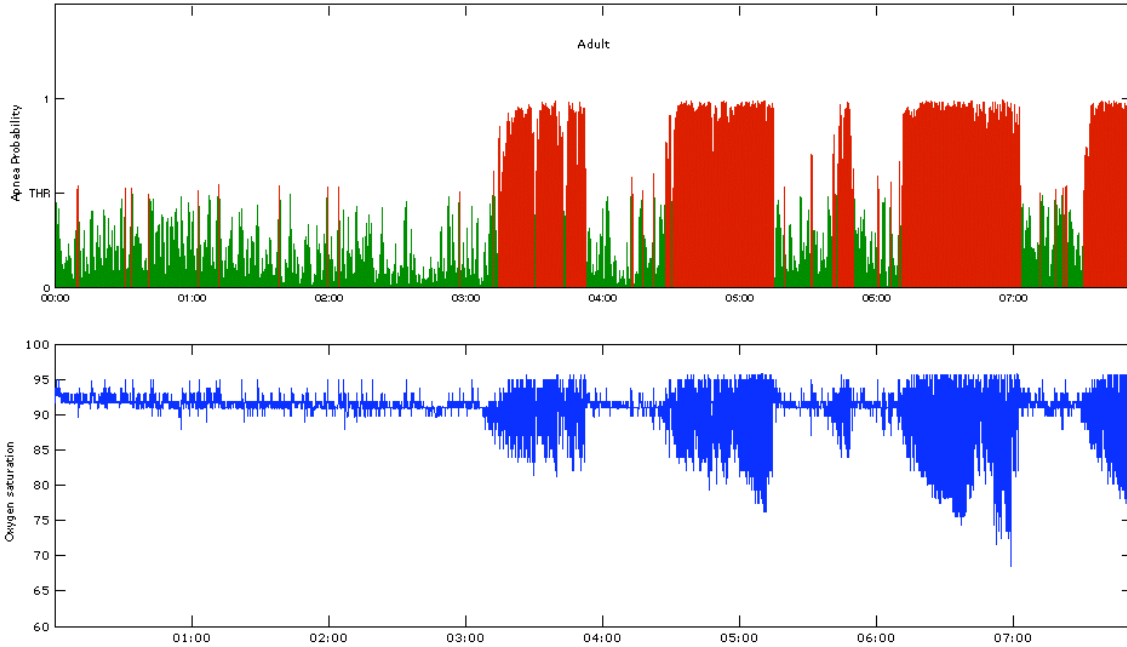


Figure 1. Holter-Oximeter report summary. Green bars represent 30 second epochs that are considered normal. Red bars are considered to be epochs during which there was apnea. The blue bars represent the oximetry tracing with corresponding hypoxia associated with the apneic events.

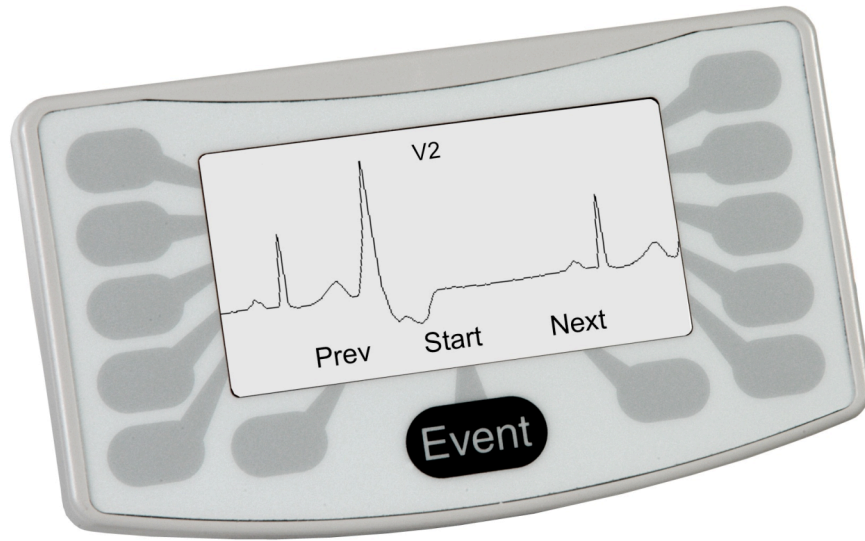


Figure 2. Oxiholter D180+. From North East Monitoring, Maynard Mass, USA.

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