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## ORIGINAL RESEARCH

# A comparison of polysomnography and the SleepStrip in the diagnosis of OSA

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**OBJECTIVE:** To investigate the role of a portable screening device (SleepStrip) in the diagnosis of obstructive sleep apnea (OSA).

**METHODS AND MATERIALS:** Prospective, nonrandomized double-blinded single cohort study at an academic health center. Patients with suspected OSA scheduled for an attended overnight Level I polysomnogram (PSG) and who consented to participate in the study wore the SleepStrip device at home the night after the PSG. The apnea-hypopnea index (AHI) determined by PSG was compared with the results of the SleepStrip recording.

**RESULTS:** Thirty-seven patients with a mean age of  $52.1 \pm 12.2$  years and mean body mass index of  $35.7 \pm 5.2$  participated in the study. The overall agreement between the AHI and the SleepStrip results using Cohen's Kappa value was 0.139 ( $P = 0.19$ ). The sensitivity and specificity of the SleepStrip for diagnosing severe OSA when the AHI was  $>40$  were 33.3% and 95% ( $P = 0.05$ ). When the AHI was  $>25$ , the SleepStrip sensitivity and specificity were 43.8% and 81.3% ( $P = 0.26$ ). The sensitivity and specificity of the SleepStrip for diagnosing OSA in patients with an AHI  $>15$  were 54.6% and 70%, respectively ( $P = 0.26$ ).

**CONCLUSION:** The SleepStrip has a low correlation with the AHI as measured by PSG. Further studies are needed before this device can be recommended as a screening tool for the diagnosis of OSA.

**EBM rating: B-2b**

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Sleep disordered breathing (SDB) is a spectrum of diseases that includes snoring, upper airway resistance syndrome, and obstructive sleep apnea (OSA). Obstructive sleep apnea is a common sleep disorder. Young et al<sup>1</sup> studied 602 state employees who had undergone an attended overnight polysomnography and found that the incidence of SDB was 24% in men and 9% in women. Most of these patients fail to be identified; it is estimated that up to 93% of females and 82% of males with moderate to severe OSA remain undiagnosed.<sup>2</sup>

It is known that SDB has profound effects on the cardiovascular and respiratory systems and neuro-cognitive function. The Sleep Heart Health Study and the Wisconsin Sleep Cohort<sup>3,4</sup> have demonstrated a strong link between SDB and hypertension. This is believed to be due to sleep fragmentation, intermittent hypoxemia, and increased sympathetic tone.<sup>5</sup> Peppard et al<sup>4</sup> demonstrated that patients with an apnea-hypopnea index (AHI)  $>15$ , had a 2.89-fold greater chance of developing hypertension than those with a normal AHI. Shahar et al<sup>6</sup> showed that there was a relative risk of 2.38 for congestive heart failure and 1.58 for cerebrovascular disease in patients with an AHI  $>11$  compared with normal patients. Therefore, it should be an essential public health priority to identify patients with OSA in order to prevent subsequent cardiovascular and cerebrovascular morbidity and mortality.

The demand for diagnostic procedures/devices for patients with suspected OSA exceeds the available supply.

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The gold standard for diagnosing OSA (the attended overnight Level I polysomnogram) is expensive, labor-intensive, and cumbersome; this has resulted in long waiting lists for studies. Consequently, many investigators have explored the use of single and/or multiple channel ambulatory monitoring systems that have emerged to assess the presence and severity of OSA. These devices are designed to aid the physician in decision-making and should be used with prudence; most are still undergoing validation.

The ideal screening device for OSA should be inexpensive, widely accessible, easily used with minimal instructions, have no risk or side effects to the patient, and be accurate. It should be capable of being issued by relatively unskilled staff, and even sent through the mail in order to reduce patient travel and staff costs. Shochat et al<sup>7</sup> introduced one such device in 2002 called the SleepStrip. The current investigation proposes to validate the reliability and predictive capability of the SleepStrip.

## METHODS

### Study Design

Thirty-nine consecutive adult patients referred to the Georgia Sleep Center for an attended overnight Level I polysomnography were prospectively enrolled over a 2-month period (10/1/2004 to 11/30/2004). All patients gave informed consent to wear the SleepStrip device at home the night after the polysomnogram. The procedure of use was explained to each patient individually according to the instruction guidelines provided with the device. The protocol was approved by the Institutional Review Board committee at the Medical College of Georgia.

### Polysomnography

All patients underwent an attended, overnight Level I PSG in the hospital. Airflow during sleep was measured with standard nasal and oral thermistors. Two separate respiratory effort channels (thoracic and abdominal belts) were used and body position was recorded. Sleep stage was evaluated with continuous monitoring of 4 electroencephalogram (EEG) channels, and 2 electro-oculogram (EOG) channels. Other additional parameters monitored included electromyogram of the chin (EMG), electrocardiogram (EKG), limb movements, pulse oximetry, and snoring sound level. Polysomnographic variables assessed included sleep parameters, sleep staging, sleep time, sleep latency, sleep efficiency, REM and non-REM events, arousals, respiratory events including the apnea-hypopnea index (AHI), oxygen desaturations, snoring level, body position, and limb movements.

Respiratory events were scored as either apneas or hypopneas. An apnea was defined as cessation of airflow for  $\geq 10$  seconds. A hypopnea was defined as a reduction of airflow for  $\geq 10$  seconds associated with at least a 30% reduction in thoraco-abdominal movement or airflow and

with at least 4% oxygen desaturation or the presence of an arousal. An arousal would be defined as an increase in EEG activity, usually alpha, more than 3 seconds on EEG in REM sleep and associated with increased EMG reading in NREM sleep. The AHI is represented by the sum of the apneic and hypopneic events per hour of sleep. The sleep technologist and the board certified sleep physician scored all the polysomnograms.

### SleepStrip

The SleepStrip is a screening device encompassing signal detection, acquisition, and display in a single disposable package (Fig 1). The device, which is self-adhesive, is placed on the upper lip at bedtime and adjusted so that respiration is detected, signaled by a flashing light. The flow signals are derived from 3 thermistors (2 nasal and 1 oral). The signal is processed 10 times each second by the SleepStrip's internal microprocessor (CPU). The CPU tracks the signal continuously, calculating the average amplitude of normal respiration cycles, peak-to-peak amplitude for each consecutive breath cycle, and the other parameters of the respiration pattern. The data are processed in the CPU and the result is displayed on the SleepStrip single digit display area. The display consists of a single digit that appears in black against a silver background. The final score (result) represents 5 possible test outcomes based on the sleep apnea severity level: 0, no apnea, comparable to a sleep lab AHI of less than 15; 1, mild sleep apnea, comparable to a sleep lab AHI between 15 and 24; 2, moderate sleep apnea, comparable to a sleep lab AHI between 25 and 39; 3, severe sleep apnea, comparable to a sleep lab AHI of more than 40; and E, error in measurement.

The display panel result is permanent, and the SleepStrip is kept as a hard copy record. All of the patients' results were read independently by 2 of us who were blinded to the results of the polysomnogram.

The SleepStrip CPU defines an apnea when the respiration amplitude drops to under 12% of the average for more than 10 seconds. A hypopnea event is defined by a decrease in respiration amplitude to less than 50%, but more than 12%, of the mean for more than 10 seconds. Respiratory events (apneas and hypopneas) are counted for the duration of the study, and the final result is displayed as a single digit.

### Statistics

We used Cohen's kappa to assess the level of agreement between SleepStrip scores and the laboratory based AHI, and we used an exact test (Proc Freq procedure in SAS) for determining whether these 2 measures showed significant agreement. The Proc Freq procedure in SAS was also used to calculate sensitivity and specificity for SleepStrip diagnosis, as well as to determine if the association between the 2 methods was significant using Fisher's exact test. We used a paired *t* test (Proc Means procedure in SAS) to determine whether the duration of sleep differed between the polysomnography in the laboratory and the SleepStrip at home.

**RESULTS**

A total of 39 patients (17 men and 22 women) were recruited for the study, the mean age was 52.1 ± 12.2 years (range, 18 to 79 years), and the mean BMI was 35.7 ± 5.2 (range, 17.7 to 46.8). The mean Epworth sleepiness score was 14.9 ± 3.5 out of a possible 24 (range, 2 to 20). A total of 37 SleepStrips were returned. One patient had a suspected adhesive allergy and withdrew from the study; 1 patient could not be contacted. One patient had to repeat the study as the SleepStrip fell off after 1 hour of commencing the study. Although there was 1 patient with a mustache, he was able to complete the study. Three patients reported that they had poor sleep quality on the night of the SleepStrip; they slept a mean of 5.4 hours. One SleepStrip indicator light did not flash throughout the night, however, it did give a display result of “0.”

Five SleepStrips reported an “E” (error) on the SleepStrip (13.5%), whereas the other 32 gave a reading of, either “0,” “1,” “2” or “3” (Table 1). There were 17 (53.2%) SleepStrip results with a “0” reading; 5 (15.6%) SleepStrip results with a “1”; 5 (15.6%) SleepStrip results with a “2”; and 5 (15.6%) SleepStrip results with a “3.”

The mean AHI was 32.1 ± 20.2, with a range of 0.4 to 111.2, while the mean AI was 11.3 ± 6.5, with a range of 0.1 to 74.9. The overall agreement, using the Cohen’s Kappa value, between the AHI and the SleepStrip results was 0.139 (*P* = 0.19) (Table 1). The sensitivity and specificity for diagnosing OSA (AHI >15) were 54.6% and 70%, respectively (*P* = 0.26). When the threshold for OSA was set at an AHI >25, the sensitivity was 43.8% and the specificity was 81.3% (*P* = 0.25). For diagnosing severe OSA (AHI >40), the sensitivity was 33.3% and the specificity was 95% (*P* = 0.05) (Table 2). The mean patient-reported sleep time for the SleepStrip was higher at 6.25 ± 1.01 hours, whereas the mean sleep time for the polysomnography was 5.73 ± 1.12 hours (*P* = 0.052).

**DISCUSSION**

Sleep-disordered breathing is a chronic, debilitating disease that results in significant cardiovascular and cerebrovascular

**Table 2**  
Sensitivity and specificity of SleepStrip vs polysomnogram

	AHI >15	AHI >25	AHI >40
Sensitivity	54.60%	43.80%	33.30%
Specificity	70%	81.30%	95%
<i>P</i> value	0.26	0.25	0.05

AHI, Apnea-hypopnea index.

morbidity and mortality. Marti et al<sup>8</sup> showed that the mortality rate for untreated severe OSA was 23.5% in a 10-year follow-up. Mortality was mainly due to cardiovascular and respiratory causes. Obstructive sleep apnea when undiagnosed results in significantly higher medical costs compared with age- and sex-matched patients who are diagnosed. Kapur et al<sup>9</sup> reports that untreated OSA may cost the U.S. health care system up to \$3.4 billion annually. This great financial burden justifies the search for an inexpensive and straightforward means for diagnosing OSA, like portable home-screening devices.

The SleepStrip has a number of characteristics that give it potential as a screening device for OSA. It is small, lightweight, cheap, convenient, easy-to-use, and safe. It is worn underneath the nose and above the upper lip. The device is comprised of flow sensors (oral and nasal thermistors), real-time analysis hardware and software, and a miniature display unit.

European and Asian investigators have reported promising results with the SleepStrip. Shocat et al<sup>7</sup> studied 288 patients with the SleepStrip and obtained a sensitivity of 70% to 88% and a specificity of 57% to 94%, depending on the severity of the SDB. For an AHI of >10, the sensitivity was 86% and the specificity was 57%; for an AHI of >20, the sensitivity was 80% and the specificity was 70%; for AHI of >40, the sensitivity was 80% and the specificity was 86%. Lavie et al<sup>10</sup> reported on a cohort of 20 patients and showed the sensitivity and specificity were 86.6% and 80%, respectively, for an AHI >10. They concluded that the SleepStrip might be a reliable aid in screening for OSA. However, Hollingworth et al<sup>11</sup> mailed the SleepStrips to 48 patients with instructions in the kit and found that the correlation of the SleepStrip data and the PSG data were poor. They qualified that this was likely a result of poor compliance and that patients need more instructions than those given in the kit manual.<sup>11</sup> They therefore concluded that the SleepStrip was not suitable for unsupervised postal screening of OSA.

Our data showed that there was an overall lack of agreement between the polysomnography and the SleepStrip, with a correlation of only 0.139 (*P* = 0.19). The sensitivities at AHI >15, >25, and >40 were poor, as were the specificity at AHI >15 and AHI >25. It was only useful in excluding severe OSA (AHI >40) for which a specificity of 95% was achieved. We observed an overall underestimate of the severity

**Table 1**  
Measure of agreement between PSG AHI and SleepStrip result (n = 32)

PSG	SleepStrip results			
	0	1	2	3
AHI 0-14.9	7	2	1	0
AHI 15-24.9	3	1	2	0
AHI 25-39.9	2	1	0	1
AHI >40	5	1	2	4

AHI, Apnea-hypopnea index; PSG, polysomnogram.

of the OSA in the SleepStrip compared with the Level I PSG. This discrepancy could not be explained by the sleep times, as the mean patient reported sleep time for the SleepStrip was higher ( $6.25 \pm 1.01$  hours) than that of the polysomnography ( $5.73 \pm 1.12$  hours) ( $P = 0.052$ ).

There are a number of limitations to the current study, the most significant limitation of this study is that the SleepStrip device and the polysomnography could not be conducted simultaneously. We are therefore unable to eliminate the night-to-night variability as a potential confounding factor, which may have contributed to the difference in the tests results. However, there are numerous studies that have shown that the night-to-night variability in sleep studies is modest. Masaquel et al<sup>12</sup> reviewed the polysomnograms in 60 patients with SDB over 2 consecutive nights and found that only 14% of the patients had crossed the AHI threshold of 5. Quan et al<sup>13</sup> studied 91 patients with SDB, and found an 85% overall correlation between night-to-night unattended home polysomnography. Stepnowsky et al<sup>14</sup> had the largest series of 1091 patients with SDB; he performed a 3 sequential night unattended home polysomnography. They found a reliability correlation coefficient of 0.88 and 0.90 for each pair of nights and concluded that there is little nightly change in SDB in the home environment. It is clear from our data that most of our patients reported longer and better subjective sleep quality during the SleepStrip night than the laboratory polysomnography. Therefore, it would be difficult to conclude that the underestimation of the SleepStrip results was due to night-to-night variability or poor sleep quality.

Another limitation that merits consideration, and which is inherent with all portable home monitoring devices, is the fact that the total sleep time for the portable home device may not reflect the true sleep time. A portable home-monitoring device is self-administered and not supervised by a sleep technician; as a result, the onset of sleep may not be accurately determined, unlike the EEG-monitored laboratory polysomnogram. This limitation may result in a tendency for the SleepStrip to underestimate the AHI.

## CONCLUSION

Given the high prevalence of OSA and the limited capacity for sleep laboratory testing, there is a clear need for home

diagnostic screening tests. The SleepStrip is small, lightweight, inexpensive, easy-to-use, and safe. However, it demonstrates low sensitivity and specificity for diagnosing mild (AHI >15) and moderate (AHI >25) OSA. The SleepStrip only demonstrated usefulness in excluding severe OSA (AHI >40). Further prospective investigation must be accomplished before the SleepStrip can be recommended as a screening device for OSA.

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