

Diagnostic Accuracy of a Portable Sleep Apnea Screener against Standard Polysomnography in Patients Referred to a Sleep Laboratory

Zahra Banafsheh Alemohammad and Arezu Najafi

Occupational Sleep Research Center, Baharloo Hospital, Tehran University of Medical Sciences, Tehran, Iran

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Abstract

Background and Objective: Obstructive sleep apnea (OSA) is a disease with serious consequences. Many portable devices have been developed to overwhelm some of limitations in the accessibility of the gold standard test for OSA, polysomnography (PSG). This study aimed to determine diagnostic accuracy of a portable sleep apnea screener against PSG in patients of a sleep clinic.

Materials and Methods: Patients admitted to a sleep lab were recruited during a three-month period. Study participants underwent one night simultaneous recording of PSG and a double channel portable sleep apnea screener in the laboratory. A sleep physician scored the PSGs manually according to standard criteria. Portable sleep apnea screener data were analyzed automatically with the manufacturer's proprietary software. We compared the apnea-hypopnea indices (AHI) from the PSG and the portable sleep apnea screener to assess the specificity and sensitivity of the device.

Results: A total of 120 patients completed the study. Mean AHI recorded from PSG and portable device were 31.7 and 30.8, respectively. Using a variety of AHI cutoff values (5, 10, 15, 20, 30 and 40), sensitivities of the portable device were 96.9, 88.6, 87.2, 84.1, 79.6, and 83.9 percent and specificities were 45.5, 71.9, 69.0, 74.5, 90.1, and 88.8 percent, respectively. The LRs+ were 1.77, 3.15, 2.81, 3.29, 8.04 and 7.49 and the LRs- were 0.06, 0.15, 0.18, 0.21, 0.22 and 0.18. The AUCs were 0.90, 0.88, 0.86, 0.89, 0.90, and 0.92, respectively.

Conclusions: In studied participants, portable device showed acceptable sensitivity and specificity in the lab when compared to the standard PSG.

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Introduction

Overnight attended laboratory-based polysomnography (PSG) with manual scoring remains the gold standard to diagnose obstructive sleep apnea (OSA) and the reference to which the other kinds of sleep screeners are compared (1-3). Despite the clear advantages of this test, certain potential limitations of it may at times interfere with the diagnostic process. PSG is time-consuming, labor-intensive, and expensive to per-

form. Patients' acceptance of in-lab testing, limited access in certain geographic areas, and long waiting lists are some of the other potential limitations (4,5). The current sleep lab capacities in many countries cannot meet the need for evaluation of OSA or other sleep disorders. Given the prevalence of OSA that is 24% in men and 9% in women (6,7), it is not surprising that a great majority of patients remain undiagnosed (8,9). These issues have driven the need to develop portable recording devices, the big advantage of which is screening for sleep apnea in different settings, such as patients' homes, hospitals, or other health care facilities (10).

Corresponding author: Z. Banafsheh Alemohammad, Occupational Sleep Research Center, Baharloo Hospital, Behdari St., Tehran, Iran.
Tel: +982155669300, Fax: +982155648189
Email: alemohammadz@yahoo.com

Portable devices are categorized into four levels: (1) standard attended PSG; (2) comprehensive portable PSG (unattended); (3) modified portable sleep apnea testing (unattended, minimum of four channels); and (4) continuous single or dual channels (11). “SleepView” sleep screener is a double-channel, wrist-worn, level-four device that measures nasal pressure for ambulatory screening of OSA.

High-level of evidence is needed to evaluate the role of a new sleep apnea screener for OSA management (12). Many devices have a failure rate that ranges from 3% to 18% as mentioned in previous studies (1). The American Academy of Sleep Medicine suggested that a portable monitoring device should have an acceptable sensitivity (sensitivity ≥ 0.825) (13). The primary objective of this study was to evaluate the sensitivity and specificity of SleepView, a portable sleep apnea screener, compared to a standard PSG in patients with or without sleep apnea admitted to a sleep laboratory.

Materials and Methods

We performed this cross-sectional study between December 2013 and March 2014 among 122 patients admitted to the Sleep Lab at Baharloo Hospital, the only teaching hospital for sleep medicine fellowship training in Tehran University of Medical Sciences. Consecutive referrals to the Sleep Clinic with OSA or other sleep disorders were invited to participate in the study.

The inclusion criteria were participants 13 years of age or older, scheduled for diagnostic PSG and willing to undergo simultaneous SleepView and PSG tests. Patients with non-respiratory sleep disorders also were recruited to capture the entire spectrum of disease. Those receiving noninvasive ventilation and supplemental oxygen were excluded. The split-night studies (14), studies with five hours or less of recording time (15) and patients who had previously been diagnosed with sleep apnea and admit-

ted for positive airway pressure (PAP) therapy or those refused to participate in the study were also excluded. Two patients revealed extremely short records in SleepView because of technical problems and were excluded from the final analysis; therefore valid data for 120 patients were entered in the final analysis of study. All patients were informed that their participation is voluntary. The study protocol was approved by the Research Ethics Committee at Occupational Sleep Research Center in Baharloo Hospital, Tehran University of Medical Sciences.

Patients underwent simultaneous PSG and SleepView tests over a single night in the Baharloo sleep lab. Although the laboratory-based PSG was supervised, no intervention regarding the SleepView recordings was performed.

The SleepView sleep screener is a double-channel portable device that measures oxygen saturation, heart rate, snoring and nasal, and oral airflow via an oronasal cannula connected to a pressure transducer. It operates on battery power and consists of a wrist-worn main device and two body sensors: oronasal airflow and finger oximeter sensor. The two nasal tubes of the SleepView and PSG cannula were inserted into the user’s nostrils to enable nasal pressure to be recorded by both devices simultaneously. Although the device can provide information about snoring, O₂ saturation and heart rate, only the Apnea Hypopnea Index (AHI) information was used in this study. The AHI used for analysis was automatically analyzed by the SleepView software and calculated by adding the total number of apneas and hypopneas per hour of recording time. The SleepView does not differentiate between wake and sleep, so the AHI measurement is based on total recording time, whereas the AHI from PSG is based on total sleep time. The SleepView does not discriminate obstructive from central apnea because it does not record respiratory efforts.

Table 1. Clinical characteristics of patients

	Mean (SD)	Minimum	Maximum
Age (year)	42.4 (1.28)	13	81
BMI (kg/m ²)	29.3 (5.5)	16.4	49.5
Min O ₂ saturation by PSG	78.1 (12.3)	42	92
AHI by PSG	31.7 (2.9)	0.1	128.8
AI by PSG	20.2 (27.1)	0	124.8
HI by PSG	11.5 (11.3)	0	63

BMI: Body Mass Index, AHI: Apnea Hypopnea Index, AI: Apnea Index, HI: Hypopnea Index. PSG: Polysomnography

Standard PSG was performed using the Embla® N7000 Recording System including electroencephalography (EEG), electrooculography (EOG); electromyography (EMG) of submental and bilateral anterior tibialis, electrocardiography (ECG); oronasal airflow measurement using nasal pressure transducer, chest and abdominal movement by piezoelectric bands; pulse oximetry, snoring, body position, and video monitoring by Infrared beams. The PSG data were manually scored using the 2007 American Academy of Sleep Medicine (AASM) guidelines for scoring of sleep and associated events, with the recommended (Type A) hypopnea criteria (16). OSA severity were defined as Mild ($5 \leq \text{AHI} < 15$), moderate ($15 \leq \text{AHI} < 30$), and severe ($\text{AHI} \geq 30$) OSA. The sleep specialist (certified by the board of registered polysomnographic technologists) that scored the PSG recordings was blinded to the SleepView results.

Descriptive statistics for the continuous variables are represented by mean, standard deviation, minimum and maximum, and for categorical variables by frequency (percentage). The SleepView recordings were compared to the standard PSG regarding speci-

ficity, sensitivity, positive, and negative predictive values (PPV and NPV), for AHI thresholds of 5, 10, 15, 20, 30, and 40. Likelihood ratio for a positive and negative test results (LR+ and LR-) were calculated to determine the practical significance of the device. Receiver operating characteristic (ROC) curves were also constructed to evaluate the area under the curve (AUC). SPSS software version 16 was used for statistical analysis and P value < 0.05 was considered statistically significant.

Finally, Bland-Altman plots were constructed. The plots are very useful graphical techniques for the examination of the patterns of disagreement between a given measurement and the gold standard. The differences between the PSG and SleepView measures were plotted against their mean value. From these plots, it is easier to assess the magnitude of disagreement, spot outliers, and to see whether there is any trend.

Results

Of the 120 patients who completed the study, 105 (87.5%) were male. A total of 22

Table 2. Predictive parameters of SleepView in AHI cutoffs of 5, 10, 15, 20, 30, and 40

	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	LR+ (95% CI)	LR- (95% CI)	AUC (95% CI)
AHI \geq 5	96.9 (0.91-0.98)	45.5 (0.26-0.65)	88.8 (81.2-94)	76.9 (46-94.9)	1.77 (1.2-2.6)	0.068 (0.02-0.22)	0.904 (0.84-0.96)
AHI \geq 10	88.6 (0.8-0.93)	71.9 (0.54-0.84)	89.7 (81.2-95)	69.7 (51.2-84)	3.15 (1.8-5.5)	0.158 (0.08-0.29)	0.887 (0.82-0.94)
AHI \geq 15	87.2 (0.77-0.92)	69.0 (0.53-0.8)	84 (74.1-91)	74.4 (57.8-86)	2.81 (1.77-4.4)	0.18 (0.1-0.34)	0.862 (0.79-0.93)
AHI \geq 20	84.1 (0.73-0.9)	74.5 (0.6-0.84)	81.7 (70-89.8)	77.6 (63-88.2)	3.29 (2.04-5.3)	0.21 (0.1-0.37)	0.892 (0.83-0.95)
AHI \geq 30	79.6 (0.6-0.8)	90.1 (0.8-0.95)	84.8 (71-93.6)	86.5 (76.5-93)	8.04 (3.9-16.5)	0.22 (0.1-0.39)	0.903 (0.84-0.95)
AHI \geq 40	83.9 (0.67-0.9)	88.8 (0.8-0.93)	72.2 (54-85.8)	94 (86.6-98)	7.49 (4.08-13.6)	0.18 (0.08-0.4)	0.926 (0.88-0.97)

AHI: Apnea Hypopnea Index; PPV: Positive Predictive Value; NPV: Negative Predictive Value; LR: Likelihood ratio; AUC: Area Under the Curve; CI: Confidence Interval

(18.3%) patients did not have OSA (AHI<5). Mild OSA was diagnosed in 20 (16.7%), moderate OSA in 29 (24.2%), and severe OSA in 49 (40.8%) patients. Table 1 summarizes the clinical characteristics of the participants.

Bland-Altman plots are shown in Figures 1-3 and illustrate the mean difference and mean \pm 2SD for AHI, AI, and HI. The mean differences (SD) were 1.1 (16), -3.6 (14.2)

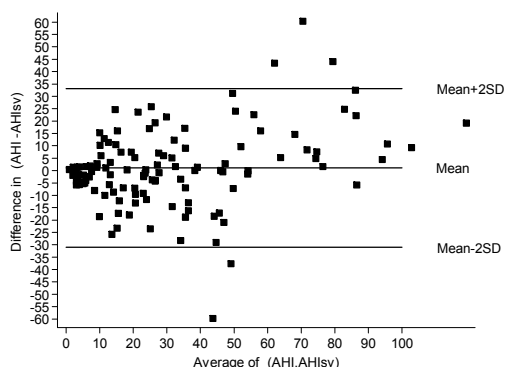


Figure 1. Bland-Altman plot for AHI measured by the PSG vs. SleepView.

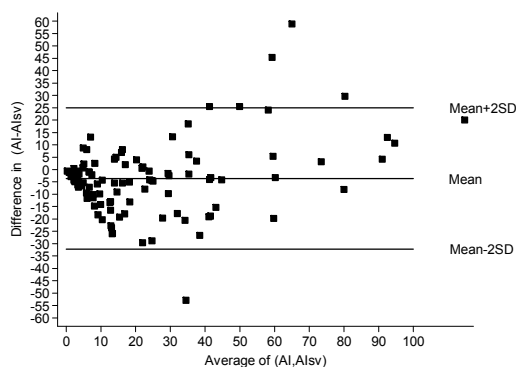


Figure 2. Bland-Altman plot for AI measured by the PSG vs. SleepView

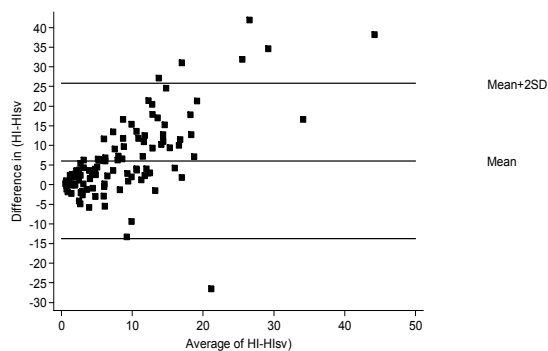


Figure 3. Bland-Altman plot for HI measured by the PSG vs. SleepView

and 6 (9.8), respectively. There are slight systematic differences between each paired measurements, as represented by the departure from zero of the horizontal lines corresponding to the mean differences.

Table 2 lists the sensitivities, specificities, PPVs, NPVs, LR_s, and AUCs of the SleepView, using a variety of AHI cutoff values (5, 10, 15, 20, 30, and 40).

Discussion

This study attempted to compare the SleepView system in the lab with standard PSG. Portable recording devices are increasingly utilized for sleep apnea diagnosis (2,17). Each of the diagnostic modalities has its own advantages and disadvantages (18). The PSG is more expensive, takes much longer to score, and requires full-time trained technologists and night-shift workers (19). Unfamiliar lab environment, which alters the patient's sleep architecture, is another limitation of PSG (4). However, PSG provides additional valuable information; such as identification of disorders related to EEG leads, the percentages of time spent in the various sleep stages and the presence of sleep fragmentation or periodic limb movement disorder (19).

Current findings showed an acceptable concordance between the SleepView and PSG when performed simultaneously in the sleep clinic. The Bland-Altman plots (Figures 1-3) revealed most of the AHI, AI and HI measurements fell within a range of 2 standard deviations from the mean values. The discrepancy between each two measurements widened as the actual values of them increase. Figure 1 presents the Bland-Altman Plot of AHI and AHIsv. This plot shows very good agreement between AHI obtained from SleepView and PSG, with a mean difference of 1.1 events/hour.

As shown in Figures 2 and 3, the differences between the SleepView and PSG in AI and HI appear to contradict each other; with the SleepView overestimating the PSG derived AI by 3.6 events/hour and underes-

timating the PSG derived HI by 6 events/hour. These findings suggest that a paired comparison of the total number of respiratory events does not indicate whether respiratory events are being detected at the same points by both devices. This may potentially overlook errors in the detection of events by the device as mentioned in previous studies (20).

When compared to standard PSG, the SleepView had a high level of sensitivity (>79%), PPV, and NPV (>70%) and a specificity of 45.5-90.1 with different AHI cutoffs from 5- 40 events/hour. It is preferable to have a screening device that provides a high level of sensitivity with acceptable specificity. Therefore, patients with sleep apnea may not be misidentified as normal by the screening device. High levels of sensitivities at all AHI cutoffs, confirmed the capacity of this device to recognize significant levels of sleep apnea, when present. At lower AHI cutoffs, the device had excellent sensitivity but a lower specificity, leading to increase in false-positive results. The best agreement with standard PSG was at cutoffs of $AHI \geq 10$, which was in line with previous studies that evaluated other portable screening devices (10).

LRs were used to determine whether a test result changes the probability of a disease. We had excellent negative LR in AHI cutoff of 5 and very good negative LRs in other cutoffs. Positive LRs were very good in AHI cutoffs of 30 and 40, and moderate in other AHI cutoffs. The high AUC values especially in extreme AHI cutoffs (5,30,40) indicated very good agreement between modalities.

In this study, SleepView was identified to have high sensitivity and acceptable specificity for OSA screening, but several limitations should be kept in mind for this portable device. This device does not record EEG, therefore sleep onset cannot be recognized and sleep stages scoring is not possible. It fails to discriminate obstructive from central respiratory events. Because it does not have a body position sensor, position-related apnea cannot be determined.

Due to such limitations, the SleepView is not indicated for patients with cardiac or respiratory diseases, and in morbid obese patients suspected to obesity hypoventilation syndrome. Therefore, like other level four devices, it can only be used under a physician's guidance for Sleep apnea screening or as an initial evaluation for patients to see if a standard PSG is required (5,21).

There are a number of limitations to the present study. Although the participants were recruited from a series of consecutive referrals to the sleep clinic, current results did not come from a community-based random sample, and as such, present findings may not be generalized to the general population. In addition, this findings are specific to a particular portable device used for the study and cannot be generalized to other level-four devices. Furthermore, this study was performed in a sleep clinic, while the SleepView system is expected to be used at the patients' home. The major difference between both environments, except for the number of electrodes attached to the patient, is attendant technicians. To minimize this limitation, no intervention about the SleepView recording was performed by technicians, although the PSG was supervised.

Further investigations are warranted to determine the predictive parameters of the SleepView in groups that are more heterogeneous and at the patients' home.

In conclusion, the current study indicated that SleepView has acceptable sensitivity and specificity in patients referred to the sleep clinic. It could be used to facilitate simple and rapid screens of patients, in situations in which standard PSG is initially impractical.

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References

1. Collop NA, Anderson WM, Boehlecke B, et al. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. Portable Monitoring Task Force of the American Academy of Sleep Medicine. *J Clin Sleep Med* 2007;3:737-47.
2. Collop NA, Tracy SL, Kapur V, et al. Obstructive sleep apnea devices for out-of-center (OOC) testing: technology evaluation. *J Clin Sleep Med*. 2011;7:531-48.
3. Fleetham J, Ayas N, Bradley D, et al. Canadian Thoracic Society 2011 guideline update: diagnosis and treatment of sleep disordered breathing. *Can Respir J* 2011;18:25-47.
4. Reichert JA, Bloch DA, Cundiff E, Votteri BA. Comparison of the NovaSom QSG, a new sleep apnea home-diagnostic system, and polysomnography. *Sleep Med* 2003;4:213-8.
5. Chen H, Lowe AA, Bai Y, Hamilton P, Fleetham JA, Almeida FR. Evaluation of a portable recording device (ApneaLink) for case selection of obstructive sleep apnea. *Sleep Breath* 2009;13:213-9.
6. Bresnitz EA, Goldberg R, Kosinski RM. Epidemiology of obstructive sleep apnea. *Epidemiol Rev* 1994;16:210-27.
7. Olson LG, King MT, Hensley MJ, Saunders NA. A community study of snoring and sleep-disordered breathing. Prevalence. *Am J Respir Crit Care Med* 1995;152:711-6.
8. Flemons WW, Douglas NJ, Kuna ST, Rodenstein DO, Wheatley J. Access to diagnosis and treatment of patients with suspected sleep apnea. *Am J Respir Crit Care Med* 2004;169:668-72.
9. Namen AM, Dunagan DP, Fleischer A, et al. Increased physician-reported sleep apnea: The national ambulatory medical care survey. *Chest* 2002;121:1741-7.
10. Erman MK, Stewart D, Einhorn D, Gordon N, Casal E. Validation of the ApneaLink for the screening of sleep apnea: a novel and simple single-channel recording device. *J Clin Sleep Med* 2007;3:387-92.
11. Ferber R, Millman R, Coppola M, et al. Portable recording in the assessment of obstructive sleep apnea. ASDA standards of practice. *Sleep* 1994;17:378-92.
12. Sunwoo B, Kuna ST. Ambulatory management of patients with sleep apnea: is there a place for portable monitor testing? *Clin Chest Med* 2010;31:299-308.
13. Kirsch DB. PRO: sliding into home: portable sleep testing is effective for diagnosis of obstructive sleep apnea. *J Clin Sleep Med* 2013;9:5-7.
14. McArdle N, Grove A, Devereux G, Mackay-Brown L, Mackay T, Douglas NJ. Split-night versus full-night studies for sleep apnoea/hypopnoea syndrome. *Eur Respir J* 2000;15:670-5.
15. Wittine LM, Olson EJ, Morgenthaler TI. Effect of recording duration on the diagnostic accuracy of out-of-center sleep testing for obstructive sleep apnea. *Sleep* 2014;37:969-75.
16. Ruehland WR, Rochford PD, O'Donoghue FJ, Pierce RJ, Singh P, Thornton AT. The new AASM criteria for scoring hypopneas: impact on the apnea hypopnea index. *Sleep* 2009;32:150-7.
17. Barak-Shinar D, Amos Y, Bogan RK. Sleep disordered breathing analysis in a general population using standard pulse oximeter signals. *Sleep Breath* 2013;17:1109-15.
18. Rosen CL, Auckley D, Benca R, et al. A multisite randomized trial of portable sleep studies and positive airway pressure autotitration versus laboratory-based polysomnography for the diagnosis and treatment of obstructive sleep apnea: the HomePAP study. *Sleep* 2012;35:757-67.
19. Tan HL, Gozal D, Ramirez HM, Bandla HP, Kheirandish-Gozal L. Overnight polysomnography versus respiratory polygraphy in the diagnosis of pediatric obstructive sleep apnea. *Sleep* 2014;37:255-60.
20. Norman MB, Middleton S, Erskine O, Middleton PG, Wheatley JR, Sullivan CE. Validation of the Sonomat: a contactless monitoring system used for the diagnosis of sleep disordered breathing. *Sleep* 2014;37:1477-87.
21. Littner MR. Portable monitoring in the diagnosis of the obstructive sleep apnea syndrome. *Semin Respir Crit Care Med* 2005;26:56-67.