Home Monitoring of Sleep Disorders

A comparison of traditional laboratory-based polysomnography and the Alice PDx portable monitoring device, and the usability of the Alice PDx.

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Study objective: To evaluate the accuracy of the Alice PDx portable monitoring device as compared to traditional lab-based polysomnography (PSG), and evaluate the usability of the Alice PDx.

Study design: Two-arm, parallel, randomized study.

Setting: Participants' homes and standard sleep laboratories (Sleep Center of Greater Pittsburgh, Monroeville, Pa., USA, and Indiana Regional Medical Center Sleep Disorders Center, Indiana, Pa., USA).

Participants: Twenty-two participants who required a diagnostic sleep study and had not undergone a PSG prior to this study.

Measurements and results: Comparison between scored staging and respiratory variables was assessed. The usability of the portable monitoring device was evaluated by two groups of participants prior to their having a home sleep study. One group of participants did not receive any instructions about the Alice PDx device, while the other group of participants received full instructions about the device.

Conclusion: The results suggest that the Alice PDx portable monitoring device is highly accurate in its ability to detect and capture respiratory events during sleep and is easy for patients to use.

Abbreviations: CPAP (Continuous Positive Airway Pressure), GSI (Good Study Indicator), PSG (Polysomnography), OSA (Obstructive Sleep Apnea)

Key words: Home diagnostics, portable monitoring, sleep apnea

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Introduction

According to the National Sleep Foundation, approximately 75 million Americans are affected by some type of sleep disorder and more than 18 million suffer from obstructive sleep apnea (OSA) alone. It is estimated that a staggering percentage of those affected, 92% of women and 80% of men, remain undiagnosed. Complications from untreated sleep disorders include excessive daytime sleepiness, and neurocognitive deficits including decreased intellectual capacity and psychomotor vigilance.[1] Additionally, patients with untreated OSA are at increased risk for diabetes, hypertension, heart failure, stroke, and other co-morbidities.[1]

Polysomnography, a method by which a patient sleeps overnight in a sleep laboratory and has various physiological signals recorded, is the most recognized and established tool used in the diagnosis of sleep disorders. However, this standard method of OSA diagnosis is expensive, resource-intensive, and sometimes inefficient.[2,3] Due to the growing recognition of the complications of sleep disorders and an increased prevalence in the number of cases diagnosed each year, there is a need for a more convenient and efficient method of diagnosis that also must maintain a high level of accuracy.[4]

Portable home-based sleep monitoring systems have recently been developed to address this need. Portable home monitoring offers the benefit of recording sleep parameters in a patient's own home, providing a natural environment (versus a sleep lab) that is typically more conducive to sleep.[5]

Several studies have concluded that portable monitoring is an effective, cost-efficient and convenient method of diagnosing sleep disorders and the procedure is becoming increasingly popular in the medical community.[2,4-7] The Centers for Medicare and Medicaid Services (CMS) has recently proposed changes to its national coverage determination for CPAP to expand coverage to include a diagnosis of CPAP made using unattended home portable monitoring.[8]

According to a recent study by the US Department of Health and Human Services, the average nationwide wait time for a single facility-based PSG is 13 weeks (4 to 26 weeks) while the average wait time for a home monitored study is only two weeks (zero to five weeks). Recent US studies suggest that the time from physician referral for a sleep study to treatment ranges from two to ten months.[1,9] Based on these statistics, portable monitoring may offer an accelerated and more efficacious path to treatment, possibly resulting in an increased quality of life and a decrease in derogatory symptoms and co-morbidities.

Several types of laboratory and portable monitoring equipment are currently on the market. These products are classified based upon the number of physiological parameters or channels they can detect. Type I devices are marketed as facility-based, not home-based, and are capable of recording approximately 14 to 16 indicative channels which accurately measure neurological, respiratory, and sleep parameters.[10] Type II devices are portable and offer at least seven channels which must include oxygen saturation, at least two airflow/effort channels, ECG/heart rate, EOG, and chin EMG.[10] Type III devices record at least four signals and must include oxygen saturation, at least two airflow/effort channels, and ECG/HR.[10] Type IV devices detect one to two parameters and are classified as anything that does not fulfill the Type I, II, or III categories.[10] Type I and II devices have the ability to detect and differentiate sleep from wake, while Type III and IV devices do not.

A novel device for the diagnosis of sleep apnea

The Alice PDx (Philips Respironics, Murrysville, PA) is a portable Type II or III diagnostic device designed to record physiologic variables during sleep. It may be used for sleep apnea and sleep-disordered breathing screening as well as for follow-up and diagnostic assessment. The Alice PDx device can be connected to a therapy device, such as a positive airway pressure (PAP) device, and used in a sleep laboratory or at home as directed by a health care provider. Data are recorded from a sleep study collected by the Alice PDx and stored on a removable data storage card. The device, however, also can be connected directly to a computer containing the Philips Respironics Sleepware software for real-time data viewing.

Color-coded labels located around the perimeter of the Alice PDx device indicate the various connection sensor leads (figure 1). The basic channel set measures oral-nasal airflow and pressure via the cannula and thermistor, respiratory effort via the abdominal and chest belts, and arterial oxygen saturation level via the pulse oximeter

(%SpO2 and pulse rate). The device also detects body position (supine or non-supine). In addition to the basic channel set indicators, the Alice PDx contains sensors for the recording of cardiac electrical activity (ECG/EKG), electroencephalogram (EEG), electrooculogram (EOG), and electromyogram (EMG).

The Alice PDx incorporates a function known as the good study indicator (GSI) that records and displays in real-time the number of hours of good quality data recorded by the device. Utilizing pulse oximetry and oral/nasal pressure and flow, the GSI function is able to determine if the signals captured by the Alice PDx are adequate and accurate. The results collected by the GSI are reported in the form of a four-quadrant pie chart displayed on the LCD screen of the PDx that shades automatically as the study progresses (figure 2).

The GSI can be configured to record as few as one hour to as many as twelve hours per night. If, upon awakening, the patient discovers that one of the sensors has become disconnected or some other problem occurred during the study resulting in poor quality signal(s), the sensor can be repositioned or the study can be repeated prior to the patient returning to the laboratory or office, saving the provider time and money.

Study methods

One challenge facing sleep professionals is knowing how accurately home-based sleep diagnostic systems compare to in-lab polysomnography in diagnosing sleep-disordered breathing. To address this, a study was performed to validate the Alice PDx against an in-lab PSG system. The study also evaluated the usability of the Alice PDx device from both a technician and patient perspective.

In this study, 22 participants (never having had a PSG prior to this study) were recruited from two sleep diagnostic laboratories and asked to perform a sleep study in their homes. Participants applied a basic respiratory configuration consisting of respiratory effort, pulse oximetry, and pressure- and thermistor-based flow. Of the 22 participants enrolled, 12 (group 1) received the Alice PDx from a sleep technician but were given little or no instruction concerning the set up or functionality of the device. The remaining ten participants (group 2) were given full instruction from a trained sleep professional. All participants were asked to read the user manual and/or watch an interactive video to gather more information on applying the basic respiratory leads and sensors.

Upon awakening, each participant viewed the Good Study Indicator and if less than 4.5 hours (3/4 of the pie shaded on the GSI) of good quality data were collected, the study was repeated on the following night prior to the participant returning to the laboratory for follow-up assessment. All participants completed an evaluation form to assess the usability and functionality of the Alice PDx device.

In a separate arm of the study, the Alice PDx was compared and validated against its predicate device, the Alice 5 PSG diagnostic system (Philips Respironics). After performing an adequate home diagnostic study (GSI ≥ 4.5 hours), 20 of the 22 participants reported to the sleep laboratory and were simultaneously hooked up to both the Alice 5 PSG system and the home monitoring device using bifurcated leads for pressure based flow, ECG, EEG, EMG, and EOG inputs. (Two of the twenty-two participants dropped out prior to the lab night evaluation due to events unrelated to the study.)

Participants received two sets of abdominal and chest effort belts, pulse oximetry sensors, and thermistors. One set was connected to the Alice 5 and the other set was connected to the Alice PDx. All sensors were virtually identical except that the thermistor used for the Alice 5 was oral-nasal and the Alice PDx thermistor was oral only. Upon completion, both the home and lab studies were centrally scored. Physiologic data recorded by the Alice PDx were compared to the data recorded by the Alice 5 and equivalence were evaluated by comparing the manual study scores for detected apnea and hypopnea events and sleep staging.

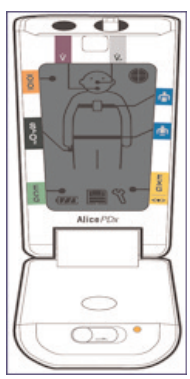

Figure 1

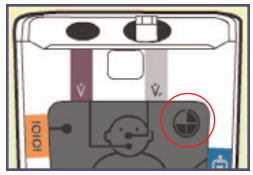

Figure 2: The GSI indicates 75% good quality

Summary of results

Usability of device

All 22 participants completed a questionnaire related to the usability of the PDx device. The results are outlined in Table 1. Overall, participants in groups 1 and 2 agreed that the device and all accessories were easy to use and apply. There were no significant differences noted between groups. Technicians (n=5) completed a separate questionnaire, similar to that given to participants, and 100% of them agreed that each individual sensor and the device in general were very easy to understand and use (data not shown).

Table 1: Participant evaluation form results (N=22)

The following symbols/accessories are easy to use and understand:

	% agreement
Symbols/color-coded labels	90.9
Flashing connection symbols	95.4
Chest effort belt	90.9
Abdominal effort belt	90.9
Cannula	100
Thermistor	95.4
Pulse oximeter	90.9
Manual*	76.2
Video	92.9
Good study indicator (GSI)	90.4
Overall general ease of use:	90.9%

*Note: The Alice PDx User Manual has been revised since this study to improve readability/usability.

The average amount of time spent reviewing the PDx setup instructions for the home diagnostic study was approximately 15 minutes. Of the 12 participants who received no device instruction (group 1), ten (83.3%) achieved a good quality study of equal to or greater than 4.5 hours, as evaluated by the GSI, on the first night (figure 3). Of the other two participants, one obtained a good quality study on the second home night by securing a better connection with the pulse oximeter.

The other participant collected, for the second time, less than 4.5 hours of good quality study because of waking earlier than expected and removing the device and all accessories prior to achieving a full study. Thus, only one participant (8.3%) failed to achieve a good study after two attempts according to the trial criteria, but this participant did obtain an adequate amount of data (defined as at least two hours of recording time) according to AASM and Medicare requirements. All of the 10 participants who received device instruction (group 2) were able to obtain a good quality study on the first night (figure 4).

Given these statistics, it appears that the device instruction helped participants set up the device but instruction may not be absolutely necessary in order to obtain a good study.

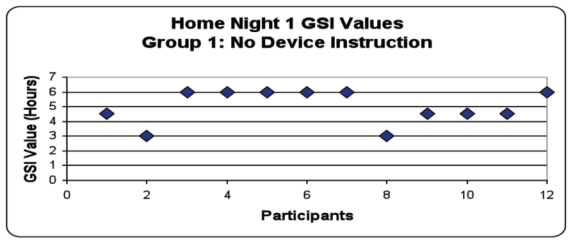

Figure 3

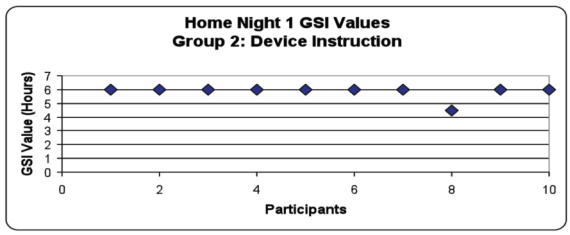

Figure 4

Alice PDx validation against PSG: staging

When comparing the 20 manually scored studies that were simultaneously collected on the Alice PDx and the Alice 5, it was found that staging agreement was highly similar. Across all 20 studies, 14,106 of the 15,464 total epochs (91.2%) were staged the same, resulting in a Kappa of 89% (table 2). As expected, sensitivity and specificity of staging were also highly correlated (table 3).

Table 2: Alice 5 and Alice PDx epoch by epoch staging data

		Alice PDx					
	Number of epochs	W	REM	N1	N2	N3	% total
Alice 5	W	2521	37	153	64	4	17.97
	REM	4	1713	19	70	0	11.68
	N1	105	49	514	114	2	5.07
	N2	53	101	156	7315	172	50.42
	N3	11	26	2	216	2043	14.86
	Percentage total	17.42	12.45	5.46	50.30	14.36	100.00
	Total epochs: 15464		Agreed: 14106			Disagreed: 1358	
		Kappa: 89%			Agreement rate: 91.2%		

Table 3: Alice 5 and Alice PDx sleep staging agreement

	Sensitivity	Specificity
Wake	90.7	98.6
REM	94.9	98.4
N1	65.6	97.8
N2	93.8	93.9
N3	88.9	98.6

Alice PDx validation against PSG: respiratory events

The difference in apnea and hypopnea values between the Alice 5 and the Alice PDx was analyzed using the non-parametric Wilcoxon Signed Rank test, and an intraclass correlation coefficient that utilized a two-way random model to assess absolute agreement for a single variable. In addition, scatter and Bland-Altman plots were generated to compare the scored events from each diagnostic system (figures 5 and 6). A two-tailed significance level of $p < 0.05$ was used for the statistical analysis.

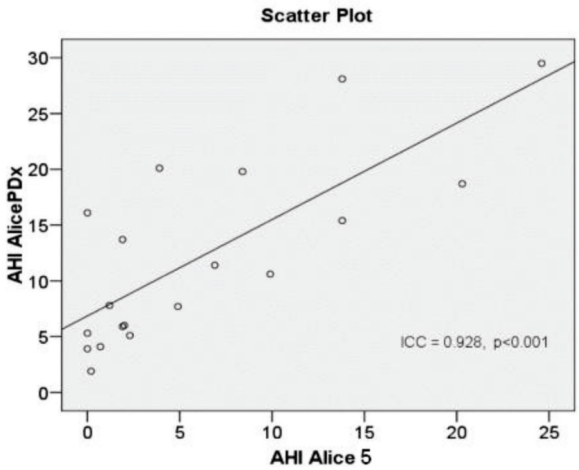

Figure 5

Figure 5. Scatter plot of AHI measured on the Alice PDx system (y-axis) vs. AHI measured on the Alice 5 system (x-axis).

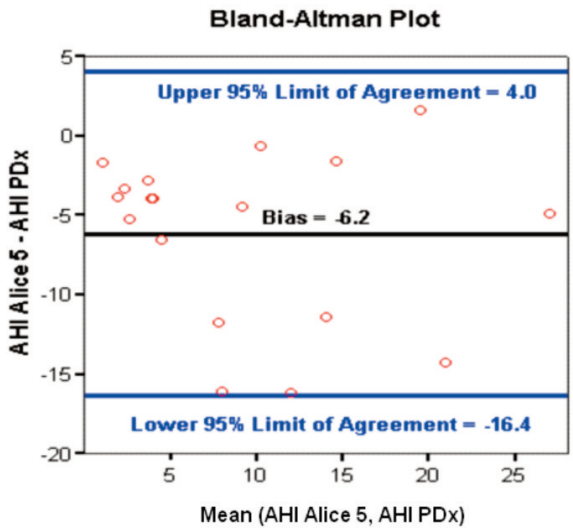

Figure 6

Figure 6. Bland-Altman plot, where the x axis represents the mean AHI between the Alice 5 and Alice PDx systems, and the y-axis represents the difference in AHI between the Alice 5 and Alice PDx systems.

*Note: For visual clarity, an outlier was excluded from the scatter plot (90.7, 99.8) and the Bland-Altman plot (95.25, -9.1), but the data from this participant was included in the analysis.

The apnea and hypopnea events captured on the Alice 5 were significantly correlated with the events captured on the Alice PDx device (intraclass-correlation-coefficient = 0.928, p <0.001) (table 4). The mean AHI for all 20 studies collected on the Alice 5 was 10.37 +/- 20.19 (S.D.), with a range of 0–90.7, while the mean AHI from the Alice PDx was 16.55 +/- 21.15 (range, 1.9 to 99.8). These results demonstrate that the Alice PDx collected an average of 6.18 more events per hour than the Alice 5 system (p<0.001).

In the literature, the mean AHI difference between portable monitoring and laboratory-based PSG ranges from 10.7 to 24.0 events per hour[10]. Thus, the higher sensitivity toward Alice PDx collecting more respiratory events than the lab-based PSG system is typical and similar to results obtained by other portable devices. It is thought that the difference in the types of thermistors that were used for the Alice 5 and Alice PDx simultaneous acquisition may have contributed to the bias. Ten additional participants will be recruited into the study and given oral-nasal thermistors for both the Alice 5 and PDx acquisition to determine if the bias decreases.

Conclusion

Overall, all 22 participants enrolled in the study, regardless of level of device instruction, were able to configure the portable monitoring device correctly in their homes and perform an adequate diagnostic study. Participants believed the Alice PDx and accessories were easy to use and set up. Technicians averaged only 15 minutes to explain the device instruction to each participant, thus potentially providing significant time and cost savings compared to an in-lab study.

Staging data collected from the simultaneous acquisition of Alice PDx and its predicate device, the Alice 5, showed high sensitivity and specificity and an agreement rate of 91.2 percent. Further, respiratory event data were highly correlated with an intraclass correlation coefficient of 0.928 (p <0.001) despite an AHI mean bias of 6.18 events per hour. The results of this study suggest that the Alice PDx home monitoring device is not only easy for patients to use, but easy for technicians to explain and highly accurate in its ability to detect and capture events from a home-based portable monitoring sleep study.

Table 4: Alice 5 and Alice PDx respiratory statistics

				Paired differences (bias)			Intraclass correlation	
Variable	Mean	Std. dev.	N	Mean	Std. dev.	p-value	Coefficient	p-value
AHI Alice 5	10.37	20.19	20	-6.18	5.20	<0.001	0.928	<0.001
AHI Alice PDx	16.55	21.15	20	-6.18	5.20	<0.001	0.928	<0.001

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