Validity of a Portable Cardio-Respiratory System to Collect Data in the Home Environment in Patients with Obstructive Sleep Apnea

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As part of the development of a portable cardio-respiratory system for detection of sleep-disordered breathing in the home, data gathered from the LifeShirt® (LS) system were compared to that from traditional polysomnography (PSG) in a laboratory environment and then again in the home to ascertain (1) the degree of concordance between the two and (2) to verify whether or not reliable data could be collected outside the laboratory. Ten subjects were recorded for one night each during three different conditions, PSG in the lab (PSG), LS and PSG in the lab (LS-L), and LS at home (LS-H).Total sleep time (p=0.097), time in stage 1+2 sleep (p=0.245), time in stage 3+4 sleep (p=0.633), REM sleep time (p=0.157), and total awakenings (p=0.364) were not different between PSG and LS-L. No significant difference between the apnea/hypopnea index (AHI) as determined by PSG (28.2+21.1/hr) LS-L (30.8+16.3/hr) and the LS-H (27.3+21.4/hr.) was observed. Oximetry data were not significantly different between the two devices (mean: PSG, 93±5%; LS-L, 92±3%; and LS-H, 92±3%; p=0.41). There was a strong linear relationship between PSG and LS-H and PSG and LS-L for AHI (r=0.96; p<0.0001 and r=0.82; p=0.004, respectively). Agreement for AHI was determined using the method of Bland-Altman (bias=0.848, SD=6.41), as well as the concordance correlation coefficient (ρ_c=0.96). Sensitivity and specificity for detection of OSA were high, but varied slightly with the threshold definition used. For an AHI of >5/hr, sensitivity and specificity were both 100%; for an AHI>15/hr, they were 87.5% and 100%, respectively.
Conclusions: In summary, a high degree of concordance between LS and traditional PSG was observed, suggesting that LS may be a viable option for the physicians to consider for home detection of OSA. **(Sleep and Hypnosis 2004;6(2):74-81)**

Key words: *Polysomnography, home monitoring, monitoring, physiologic, sleep, sleep-disordered breathing, cardio-respiratory, portable, validation studies*

INTRODUCTION

Obstructive sleep apnea (OSA) is a common disorder, reported to affect 4% of the adult population (1), and is associated with daytime sleepiness, systemic hypertension, and cardiovascular morbidity (2). Usually diagnosed by polysomnography (PSG) in the sleep laboratory, many individuals with OSA likely remain undiagnosed because of the costs and limited access associated with sleep laboratory analysis. Additionally, most sleep laboratories operate during the night and are, therefore, unavailable to accommodate individuals who do shift work. Thus, in-home sleep apnea tests have become increasingly available in response to the desire to reduce the

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cost and time to diagnosis of OSA.

LifeShirt® (LS, VivoMetrics, Inc; Ventura CA) utilizes respiratory inductance plethysmography (3,4) and pulse oximetry incorporated into a comfortable Lycra shirt to collect respiratory and saturation data from patients sleeping in their home. The LS utilizes established technologies such as fingertip pulse oximetry, for data collection, but needs to be shown to provide as effective an evaluation of OSA in the home setting as polysomnography provides in the sleep lab. While less expensive, in-home data collection is potentially vulnerable to variability in equipment set-up, protocol compliance, and patient behavior when compared to data collection in the more controlled environment of the laboratory. The present study was undertaken to compare the results for standard measures of sleep time and OSA related disturbances obtained from traditional polysomnography with the LifeShirt® in the laboratory and at home.

In practice, the development of an inexpensive and reliable system that can be used in the home may help increase detection and treatment of sleep related breathing disorders in the general population. The LifeShirt® is such a system, employing the well-recognized technique of respiratory inductance plethysmography (RIP) to assess changes in lung volume, and provide values for calibrated minute ventilation (5). In order to determine the validity of this system for identification of OSA, we compared sleep related breathing patterns in patients known to display OSA recorded by polysomnography in the laboratory and by the LS at home.

METHODS

Subjects

Ten patients (8 men and 2 women; age, 48.8±14.2 yrs; BMI, 32.4±5.6 kg/m^2; neck circumference, 41.4±4.3 cm) who were clinically suspected of having obstructive sleep apnea (Table 1) were invited to participate from consecutive patients scheduled to undergo routine polysomnography during February and March 2002 at the clinic of the Sleep Disorders Center at the Dallas Veterans Affairs Medical Center (VAMC). All patients scheduled for polysomnography were suspected of experiencing sleep disordered breathing. Their clinical complaints of sleepiness were documented by the Epworth Scale (6) (13.4±4.5).

Table 1. Characteristics and symptoms of subjects who completed the study. All values expressed as mean (±SD) unless otherwise stated.

Characteristic	Mean (SD)
Age (yr)	48.8 (14.2)
Weight (kg)	102.4 (19.1)
Height (cm)	178.3 (14.2)
BMI (kg/m^2)	32.4 (5.6)
Neck size (cm)	41.4 (4.3)
ESS	13.4 (4.5)
Symptoms	**# of patients reporting**
Loud snoring	9
Witnessed apneas	9
Non-refreshed sleep	9
Night time arousals	3
EDS	8
Morning headaches	8

n=10 (8 men, 2 women)
BMI=Body Mass Index
ESS=Epworth Sleepiness Scale
EDS=Excessive Daytime Somnolence

Protocol

Subjects suspected of having OSA underwent sleep analysis under three conditions: (1) traditional polysomnography (PSG) carried out in the sleep laboratory; (2) modified polysomnography in the laboratory, in which LS was substituted for the chest and abdominal expansion belts used in polysomnography (LS-L); and (3) sleep recording by use of the LS at home (LS-H). All three procedures were performed in random sequence and study nights were not separated by more than two weeks for any patient. Details of each testing session are below. Study

procedures were explained to the subjects, who gave written informed consent for participation in accord with the Institutional Review Board of the Dallas VAMC.

Study Procedures

Apnea/Hypopnea Identification

Respiratory events for PSG and LS studies were scored according to the criteria set forth by the American Academy of Sleep Medicine (AASM) (7). An apnea event was defined as an airflow or tidal volume amplitude reduction of >75% from baseline with a duration of at least 10 seconds; or a less significant reduction in airflow or tidal volume amplitude, but the presence of an oxygen desaturation ≥3%. A hypopnea event was defined in the same manner but utilizing a reduction of >25% from baseline in airflow or tidal volume amplitude. Apnea-hypopnea index (AHI) was the rate of apneas and hypopneas per hour of sleep.

Laboratory PSG

Laboratory PSG was performed in accordance with the standard operating procedures at the Dallas VAMC Sleep Laboratory overseen by an American Board of Sleep Medicine (ABSM) certified physician. Data collected included: two EEG channels (C3-A2 or C4-A1 and O1-A2 or O2-A1), two electro-oculographic channels (right outer canthus and left outer canthus), submental electromyogram (genioglossus), ECG, oronasal (thermistor) air flow, thoracic and abdominal effort, body position and pulse oximetry (Ohmeda, Biox, model 3700, Boulder, CO, USA). Polysomnographic recordings were scored manually and interpreted by a board certified polysomnographer for total sleep time (TST), total number of night time awakenings, and sleep staging at the Dallas VAMC Sleep Laboratory according to Rechtschaffen and Kales (8).

Home LifeShirt

The LifeShirt system (LS, VivoMetrics, Ventura, CA, USA) is a portable system that incorporates two respiratory inductance plethysmographs (RIP) (thoracic and abdominal) sewn into a Lycra vest, a pulse oximeter (Nonin, Adult Flexi-Form II, Model 7000A, Plymouth, MN, USA) an ECG, and an accelerometer. The rib cage-abdominal volume-motion coefficients for RIP signals were determined by the qualitative diagnostic calibration procedure (QDC) (9). The sum of rib cage and abdominal signals were calibrated in absolute volume units (L) by a fixed volume calibration procedure. Overnight data from these sources were stored on a memory card in a small recorder unit. In the morning, the data were transmitted via the Internet to a data processing center, where it was checked for technical quality, then assessed clinically using proprietary software (VivoLogic®) which calculates values for traditional measures of sleep-related ventilation, including the apnea/hypopnea index (AHI) and measures of oxygen saturation. Time from "lights out" to "lights on" as recorded by the patient via the LS electronic diary was used as sleep time for the calculation of AHI for the LS at home night. A registered sleep technologist and a physician certified by the ABSM then reviewed the data.

Statistical Analyses

Statistical comparison of the scoring was performed by use of SPSS for Windows 11.5 (SPSS, Inc., Chicago, IL, USA). The Pearson product-moment was used to evaluate the relationship between the calculations of AHI between the two devices. Agreement was assessed via the concordance correlation coefficient (ρ_c), as validated by Lin (10), as well as, by the method of Bland and Altman (11). Sensitivity and specificity were also determined. In consideration of the possibility that sensitivity and specificity might vary with the

Table 2. Sleep time

Comparison		Mean (minutes)	Std. Error of Mean	P value
TST	PSG	362.4	13.55	0.097
	LS-L	327.1	21.59	
# of Awakenings	PSG	38.7	8.13	0.364
	LS-L	44.4	11.88	
Stage 1+2 Sleep	PSG	243.7	9.48	0.245
	LS-L	222.4	17.47	
Stage 3+4 Sleep	PSG	60.9	11.56	0.633
	LS-L	64.9	12.26	
REM Sleep	PSG	62.6	7.06	0.157
	LS-L	46.2	8.92	

TST: Total sleep time
NOTE: all comparisons included 10 pairs, except Stage 3+4 sleep which was based on 9 pairs.

severity of the sleep-disordered breathing, the determinations were carried out using two different thresholds for a diagnosis of obstructive sleep apnea (AHI values of >5/hr and >15/hr). Linear regressions were performed to demonstrate relationships between the various conditions tested.

RESULTS

EEG

Total sleep time (TST), number of night time awakenings and sleep stage results for PSG and LS-L are contained in Table 2. Simultaneous and synchronized EEG, EOG, EMG, and pulse oximetry were recorded during LS-L as described in condition 2 above. Sleep scoring from the in-lab PSG and in-lab LS-L were compared. This comparison revealed no significant difference in total sleep time (PSG, 362.4±40.6 min; LS-L, 327.1±64.8 min, p=0.097) and number of awakenings (PSG, 38.7±24.4; LS-L, 44.4±35.7, p=0.364).

Apnea/Hypopnea/AHI

Table 3 contains the absolute respiratory and EEG data for PSG, LS-L, and LS-H. No significant difference between the apnea/hypopnea index (AHI) as determined by PSG (28.2±21.1/hr), LS-L (30.8±16.3/hr) and the LS-Home (27.3±21.4/hr) was observed.

As seen in Figure 1, a regression analysis indicated a highly significant relationship between the AHI as determined by PSG and LS-Home (r=0.96). Spearman rank correlation (non-parametric correlation) revealed similar results (ρ=0.97). When agreement was expressed as a function of mean AHI in a Bland-Altman plot, 8 of the 10 points fell within 1.0 SD of the mean bias, and there was no relationship between degree of agreement and the severity of sleep-disordered breathing when comparing PSG vs. LS-L (Figure 2A), LS-L to

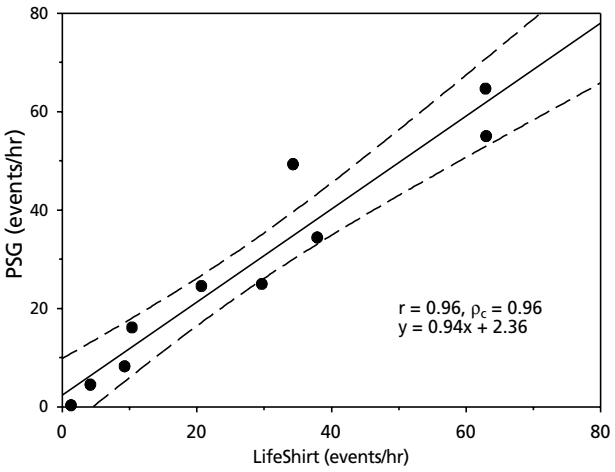

Figure 1. Regression analysis depicting relationship between PSG (lab) and LS (home) with respect to the apnea/hypopnea index. Solid line represents the regression line. Hatched lines represent the 95% confidence intervals.
n=10
r=Pearson-product moment
ρc=concordance correlation coefficient

Table 3. Individual respiratory and EEG data for PSG, LS-L and LS-H

	Subject	APNEA events	HYPOP events	AHI events/hr	S_pO_2 %	TST min	Stage1+2 min	Stage 3+4 min	REM min	Awks total #
PSG										
	1	110	117	34.4	90.7	278.0	242.5	3.0	32.5	30
	2	131	328	64.6	93.2	418.0	258.0	80.5	79.5	12
	3	48	297	49.3	87.0	362.0	232.0	81.5	48.5	25
	4	7	167	24.5	97.9	353.0	222.5	77.5	53.0	55
	5	183	246	55.0	94.0	383.5	302.5	N/A	68.0	49
	6	1	1	0.3	99.9	413.5	230.5	91.0	92.0	15
	7	122	85	24.9	86.8	360.5	279.0	20.5	61.0	101
	8	14	21	4.5	89.8	319.5	217.5	72.5	29.5	40
	9	25	35	8.2	96.4	343.0	250.0	25.5	67.5	32
	10	57	59	16.1	96.9	393.0	202.5	96.5	94.0	28
	Mean	**69.8**	**135.6**	**28.2**	**93.3**	**362.4**	**243.7**	**60.9**	**62.6**	**38.7**
	SD	**59.4**	**112.4**	**21.1**	**4.3**	**40.6**	**28.4**	**32.7**	**21.2**	**24.4**
	SE	**19.8**	**37.5**	**7.0**	**1.4**	**13.5**	**9.5**	**12.3**	**7.1**	**8.1**
LS-L										
	1	70	289	40.8	90.7	303.0	229.5	17.5	56.0	22
	2	247	184	49.5	91.0	450.5	338.0	47.0	65.5	18
	3	39	194	31.5	89.3	365.0	233.0	100.5	31.5	19
	4	89	209	42.0	91.3	310.5	177.0	95.5	38.0	43
	5	101	289	53.4	90.4	282.0	258.0	N/A	24.0	100
	6	5	28	4.5	96.3	366.0	149.5	122.0	94.5	17
	7	255	31	39.7	87.1	204.5	182.5	21.5	0.5	125
	8	99	77	24.1	95.4	268.0	169.5	43.5	55.0	39
	9	36	50	10.1	93.6	368.5	239.5	54.0	75.0	38
	10	45	51	12.3	93.2	352.5	247.5	83.0	22.0	23
	Mean	**98.6**	**140.2**	**30.8**	**91.8**	**327.1**	**222.4**	**64.9**	**46.2**	**44.4**
	SD	**81.6**	**99.2**	**16.3**	**2.7**	**64.8**	**52.4**	**34.7**	**26.8**	**35.7**
	SE	**27.2**	**33.1**	**5.4**	**0.9**	**21.6**	**17.5**	**11.6**	**8.9**	**11.9**
LS-H										
	1	117	239	37.9	90.3	N/A	N/A	N/A	N/A	N/A
	2	196	43	62.9	91.2	N/A	N/A	N/A	N/A	N/A
	3	52	236	34.3	88.5	N/A	N/A	N/A	N/A	N/A
	4	29	128	20.7	95.4	N/A	N/A	N/A	N/A	N/A
	5	293	211	63.0	91.0	N/A	N/A	N/A	N/A	N/A
	6	1	10	1.3	96.8	N/A	N/A	N/A	N/A	N/A
	7	183	69	29.6	88.8	N/A	N/A	N/A	N/A	N/A
	8	17	22	4.1	95.3	N/A	N/A	N/A	N/A	N/A
	9	27	46	9.2	94.3	N/A	N/A	N/A	N/A	N/A
	10	56	63	10.3	92.3	N/A	N/A	N/A	N/A	N/A
	Mean	**97.1**	**106.7**	**27.3**	**92.4**					
	SD	**92.1**	**85.5**	**21.4**	**2.8**					
	SE	**30.7**	**28.5**	**7.1**	**0.9**					

Hypop=total number of hypopneas
AHI=apnea hypopnea index
Mean SpO2=mean arterial saturation as estimated by finger pulse oximetry
TST=total sleep time
Awks=total number of night time awakenings
PSG=polysomnography in the lab
LS-L=PSG in lab with LifeShirt®
LS-H=LifeShirt at home
n=10

LS-H (Figure 2B), or PSG to LS-H (Figure 2C). Sensitivity and specificity for determining a diagnosis of OSA varied slightly as a function of the AHI threshold utilized. For a value of >5/hr, sensitivity and specificity were both 100%. At AHI >15/hr, sensitivity and specificity were 85.7% and 100%, respectively. Consistency of the AHI analyses in the three conditions can be observed in Figure 3 where the regression results for each individual test are presented together.

There were also no observed differences in mean pulse oximetry between PSG and LS-L (mean S_pO_2: PSG, 93±5%; LS-L 92±3%; p=0.41).

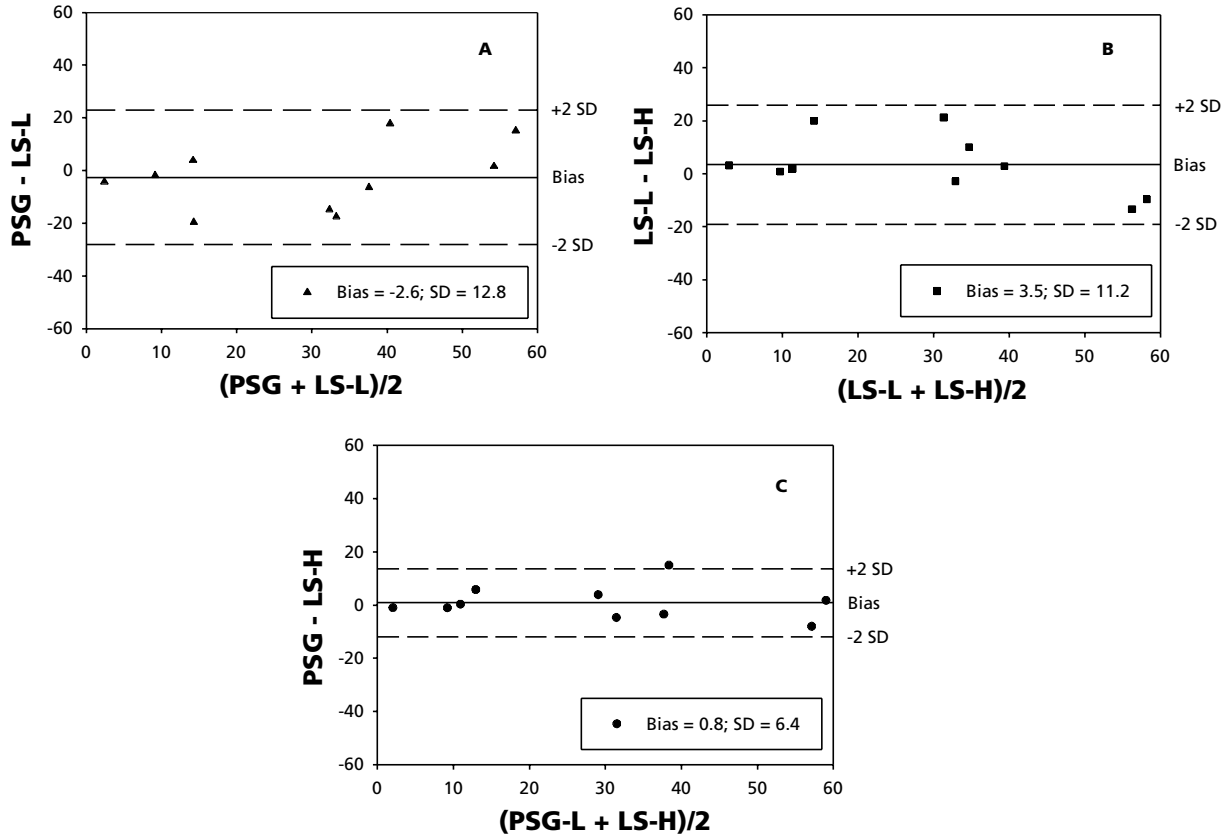

Figure 2. Mean against difference plots for PSG, LS-L and LS-H.
LS-L=LifeShirt® and PSG in lab
LS-H=LifeShirt® at home
n=10 for each comparison

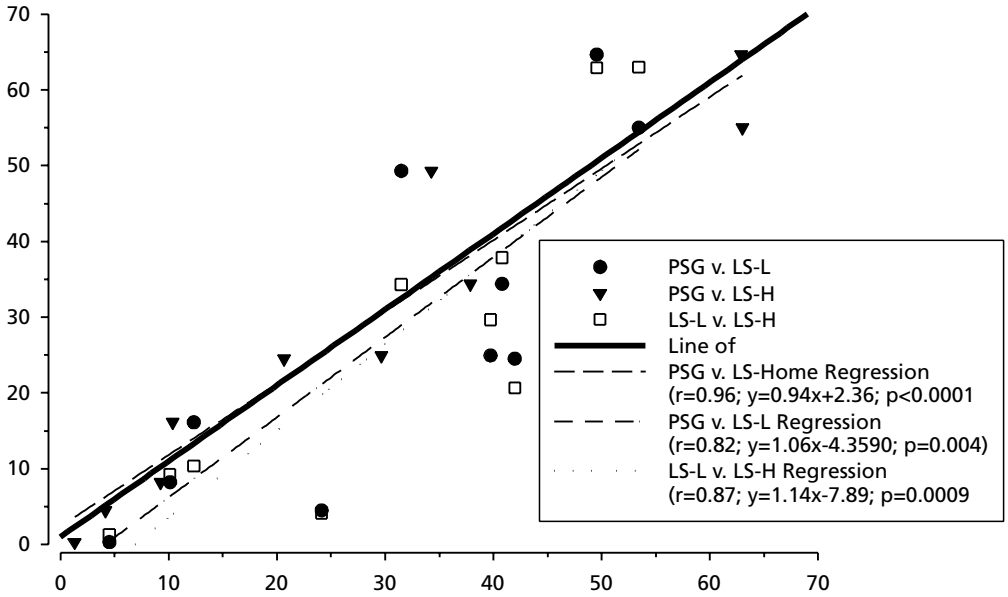

Figure 3. Regression analysis depicting relationship between PSG (lab) LS-L and LS-H with respect to the apnea/hypopnea index. Solid line represents the line of identity.
LS-L=LifeShirt® and PSG in lab
LS-H=LifeShirt® at home
n=10 per comparison

DISCUSSION

There was a high degree of agreement between sleep disordered breathing results from recordings by laboratory polysomnography and the LifeShirt® in this population of mostly middle-aged, somewhat obese patients selected because of a history suggestive of OSA. The accuracy of LS did not vary with the severity of sleep-disordered breathing (AHI) as demonstrated with Bland-Altman analysis. Additionally, sleep time and distribution of sleep stages were similar suggesting that the LS provides equivalent results for these analyses.

In considering the design of the study, there were several possible approaches for comparing the two systems. Ideally, one would record using both systems simultaneously. This would eliminate the possibility of spurious results due to night-to-night variability in degree of sleep-disordered breathing. We chose not to do so, because of the physical difficulty of placing respiratory belts for polysomnography and LS on the patient together, and because of the possibility that in this situation (which would not be used clinically) the two might somehow interact. Rather, we chose to record on two different nights in two different settings (laboratory and home, respectively) in order to gain the advantage of testing the systems as they would be used in practice. This decision allowed the possibility that night-to-night variability in severity of sleep-disordered breathing might result in a spuriously low agreement between the two methods. However, there was a high degree of agreement between the two systems, in two different settings suggesting consistency in both sleeping pattern and performance of the LS and PSG. It is unlikely that the error rates and direction would have coincidently occurred in such a way as to result in an inappropriate appearance of agreement.

The night-to-night variation in OSA has been assessed in several studies. In one series, 46 patients with a mean age of 50 who were found to have an AHI>5/hr were re-recorded; the rate of discordance between the two nights was 8% (4). The correlation coefficient for AHI between the two nights was 0.86. In middle aged volunteers, the correlation coefficient of the desaturation index (number of desaturations per hour) was found to be 0.79 (5). In healthy elderly subjects, the discordance rate, using a cutoff of AHI > 5/hr, has been reported to be 43% in a three night study (6). Thus, the degree of variability between the laboratory polysomnographic recordings and LS at home was substantially less than the expected night-to-night variability. These comparisons show that the LifeShirt® can be a useful addition to the physician's armamentarium by allowing the detection of OSA in the home setting, thus avoiding the scheduling difficulties and inconvenience of using a traditional PSG sleep lab.

CONCLUSION

PSG and LifeShirt in the laboratory setting showed similar values for the main measures of sleep architecture. Similarly, PSG in the laboratory was concordant with both LS in the laboratory and LS at home for measures of sleep-disturbed respiration. While the LS didn't incorporate EEG in the home condition (e.g., LS-H) at the time of the study it provided similar results for sleep disordered breathing utilizing patient recorded approximate sleep time. Also, the LS did not appear to cause any sleep disturbance relative to the other conditions tested. The LifeShirt appears to provide a reasonable alternative to the traditional PSG sleep lab for the assessment of sleep disordered breathing.

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