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UTILITY OF APNEALINK™ FOR THE DIAGNOSIS OF SLEEP APNEA-HYPOPNEA SYNDROME

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Abstract Portable sleep studies may play an important role to take decisions on patients referred for suspicion of Sleep Apnea-Hypopnea Syndrome (SAHS). The aim of this study was to evaluate the diagnostic accuracy of automated analysis of ApneaLink™ in patients with suspicion of SAHS. All participants (75) performed the ApneaLink and polysomnography (PSG) simultaneously in the sleep laboratory. The two recordings were interpreted blindly. The ApneaLink software calculated: (1) risk indicator (RI)-a combination of apnea/hypopnea index (AHI) plus inspiratory flow limitation events and (2) the AHI. ApneaLink™ and SAHS were defined in three ways: AHI or respiratory disturbance index (RDI) ≥ 5, 10 and 15 respectively. ROC curves analysis was performed. The sensitivity (S), specificity (E) and positive and negative likelihood ratio (LR+, LR-) for the different thresholds for RI or AHI were calculated; 66 patients were included (47 men, mean age 51, median RDI 10.6, mean BMI 29.3 kg/m^2). The best cut off points of RI were: SAHS = RDI ≥ 5: RI > 9 (S 80%, E 100%, LR- 0.20); SAHS = RDI ≥ 10: RI > 13 (S 92%, E 93%, LR+ 13.7 LR- 0.089); SAHS = RDI ≥ 15 =: RI > 16 (S 93.5%, E 91%, LR+ 10.9, LR- 0.071). The AHI had a similar diagnostic accuracy to RI for the different definitions of SAHS. The RI and AHI obtained from automated analysis of ApneaLink™ were highly sensitive and specific to diagnose moderate to severe SAHS.

Key words: sleep disordered breathing, sleep apnea, sleep apnea syndrome, home sleep study, portable sleep study

Resumen ***Utilidad del ApneaLink™ para el diagnóstico del síndrome apnea-hipopnea del sueño***. Los equipos portátiles para estudios del sueño pueden tener un rol importante para tomar decisiones en pacientes con sospecha de Síndrome Apneas-Hipopneas del Sueño (SAHS). El objetivo del estudio fue evaluar la exactitud diagnóstica del análisis automático del ApneaLink™ en pacientes con sospecha de SAHS. Setenta y cinco sujetos realizaron simultáneamente el ApneaLink™ y una polisomnografía (PSG) en el laboratorio de sueño. Los dos registros fueron interpretados en forma ciega. Un programa calculó: (1) el índice apnea/hipopnea (IAH), (2) el indicador de riesgo (IR)-IAH más respiraciones con limitación al flujo aéreo. ApneaLink™ y SAHS fueron definidos como: IAH o IPR (índice de perturbación respiratoria) ≥ 5, 10 y 15 respectivamente. Se calcularon la sensibilidad (S), especificidad (E) y razón de probabilidad positiva y negativa (RP+, RP-) para los diferentes puntos de corte fueron calculadas. Se incluyeron 66 pacientes (47 varones, edad media 51, IPR mediano 10.6, IMC medio 29.3 kg/m^2). Los mejores puntos de corte del IR fueron: SAHS = IPR ≥ 5: IR > 9 (S 80%, E 100%, RP- 0.20); SAHS = IPR ≥ 10: IR >13 (S 92%, E 93%, RP+ 13.7 RP- 0.089); SAHS = IPR ≥ 15: IR > 16 (S 93.5%, E 91%, RP+ 10.9, RP- 0.071). El IAH tuvo una exactitud diagnóstica similar al IR para las diferentes definiciones de SAHS. El IR y el IAH obtenidos del análisis automático del ApneaLink™ fueron muy sensibles y específicos para diagnosticar SAHS moderado a grave.

Palabras clave: desorden respiratorio del sueño, apnea del sueño, síndrome apnea del sueño, estudio de sueño

Sleep Apnea-Hypopnea Syndrome (SAHS) is a major health problem due to its prevalence rates of 2-4% in middle-aged people[1]. Significant morbidity[2, 3] and mortality[4] have been reported in patients with SAHS. The American Academy of Sleep Medicine recommends polysomnography (PSG) for determining the severity of sleep apnea as well as evaluating the patient's response to its treatment[5]. This approach for a prevalent pathology results in an unavoidable discrepancy between the service demand and the capacity of the sleep laboratory. Current estimates reveal that 93% of women and 82% of men with moderate to severe sleep apnea remain undiagnosed[6]. Owing to the cost, the requirement for technical expertise and the accessibility to diagnosis[7], a number of alternatives to PSG have been proposed[8]. Several studies have assessed the performance of devices based on nasal pressure to identify patients with SAHS. Most of them are sparsely portables to be used at home[9-13]. The ApneaLink™ device is a single-channel screening tool

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for sleep apnea. The device consists of a nasal cannula attached to a small case that houses a pressure transducer. The device is held in place by a belt worn around the user's chest. Up to date, three studies have evaluated the performance of ApneaLink™ or similar portable devices to detect SAHS in a group of patients with suspicion of SAHS[14, 15] or diabetes type 2[16]. The results demonstrated a high sensitivity and specificity of AHI obtained from these equipments compared with the AHI from the simultaneous polysomnographic study at all AHI levels, with the best results at an AHI of 10 or 15 events per hour. The ApneaLink™ device can provide besides of the apnea-hypopnea index, information regarding inspiratory flow limitation and to generate a risk indicator (RI). The RI is a combination of AHI plus inspiratory flow limitation events. However, there are no previously published studies about the diagnostic capacity of RI for the diagnosis of SAHS. Thus, the primary purpose of this study was to evaluate the diagnostic performance of automatic RI provided by the ApneaLink™ device in a group of SAHS-suspected patients referred to the sleep laboratory.

Materials and Methods

A prospective clinical study was performed in 76 consecutive patients referred to the *Hospital Alemán* Sleep Laboratory for investigation of possible SAHS. The recruitment period extended from July 2007 to November 2007. The inclusion criteria were SAHS- suspected patients of both sexes (snoring with/without other symptoms such as apneas referred by someone and/or somnolence), age equal to or over 18 years old and informed consent. The patients who used oxygen, CPAP or some modality of noninvasive mechanical respiratory assistance during PSG were excluded from the study. The polysomnographies with artefacts in EEG or respiratory channels (airflow, thoracoabdominal movements and SO_2) that did not allow the reading of the sleep stages or the respiratory events or with less than 180 minutes of total sleep time and the recordings of ApneaLink™ with less than 4 hours of evaluation period were not considered for analysis. All the patients had a PSG and an ApneaLink™ performed simultaneously in the sleep laboratory. An institutional review board approved the study protocol. All the patients underwent overnight PSG with a computerised polysomnographic system (BIOPC or NEUROTRACE; Akonic, Buenos Aires, Argentina), including electroencephalogram (FP1/A2, F3/A2, C3/A2, and O1/A2), bilateral electrooculogram, submental electromyogram, bilateral leg electromyogram and electrocardiogram. Oronasal airflow was measured by thermistors, respiratory effort was assessed by thoracic and abdominal piezoelectric belt and oxygen saturation (SO_2) was recorded using a finger probe (Novametrix 505 or 520, CT, USA). The oximeters employed an averaging time of 2 s. The PSG were registered from 10.30 - 11.30 PM to 05-06 PM. On the day of the study, the patients were given the following instructions: to avoid napping and not to drink alcohol or beverages with caffeine (coffee, tea and cola drinks); to continue the usual medication; to eat supper between 8.30 and 9.30 PM and to report to the sleep lab between 10.30 and 11.30 PM. PSG reading was performed manually by a widely-experienced medical staff, which was blind to the operator that analysed the ApneaLink™. The sleep stages were analysed in 30 s epochs according to international criteria[17]. The arousals were identified following the American Sleep Disordered Association recommendations[18]. The following definitions were used: apnea: absence of oronasal airflow lasting ≥ 10 s; obstructive apnea: presence of respiratory effort; central apnea: absence of respiratory effort; mixed apnea: initial central component followed by an obstructive component. Hypopnea: discernible reduction of airflow (thermistors) and/or any descends in thoracic, abdominal or both signals with respect to baseline, associated to a fall in $SO_2 \geq 3\%$ or final arousal. Respiratory effort related arousal (RERA): an arousal was considered to be due to RERA if all the following were present: alteration of the inspiratory contour in the waves from the thoracoabdominal bands in two or more breaths before the arousal, with or without discernible reduction of the thoracoabdominal bands amplitude and normalisation of the previous alteration coinciding with the arousal[19]. RERA index was defined as the total number of RERA divided into the number of hours slept. Respiratory disturbance index (RDI): number of apneas plus hypopneas plus RERA per hour of sleep[20]. Apnea-Hypopnea index (AHI): number of apneas plus hypopneas per hour of sleep. Sleep Apnea-Hypopnea Syndrome (SAHS) was defined in three different ways: RDI ≥ 5, 10 and 15. Severity of SAHS: mild = RDI ≥ 5 - < 15; moderate = RDI ≥ 15 - < 30; severe RDI ≥ 30[21]. The ApneaLink™ was used to compare its diagnosis accuracy with respect to PSG. This device registers the patient's breathing with the nasal pressure cannula. The nasal pressure is measured directly at the nostrils, and is not linear to the patient's breathing flow. In order to re-establish this linearity, a mathematical formula is used for linearizing the nasal pressure. The linearization ensures that even the smallest changes in the patient's breathing flow are recorded and evaluated validly[22].

The ApneaLink™ device operates on battery power, has a sampling rate of 100 Hz, and a 16-bit signal processor. The internal memory storage is 15 MB, which allows for approximately 10 hours of data collection. The ApneaLink™ default settings for apneas and hypopneas were used in this study. An apnea was defined as a decrease in airflow by 80% of baseline for at least 10 seconds. The ApneaLink™ default maximum apnea duration was set at 80 seconds. A hypopnea was defined as a decrease in airflow ≥ 50% of baseline for at least 10 seconds. The ApneaLink™ default maximum hypopnea duration was set at 100 seconds. The software reports apneas, hypopneas, flow limitation, snoring, the apnea/hypopnea index (number of apneas plus hypopneas per hour of evaluation period) and the risk indicator (RI). The evaluation period is the total recording time minus the record time not considered in the análisis (invalid data, missing data, start of evaluation, end of evaluation, signal too small-signal quality cannot be analyzed- and analysis exclusions). The ApneaLink does not discriminate obstructive from central events because the signal is based only on airflow, and there is no recording of respiratory effort. The RI is calculated according to the following equation:

RI = point score as a sum of AHI + score of FL/FS

The points calculated from AHI correspond to AHI x 1 h = number of points (e.g. AHI = 5/h x 1 h = 5 points). The FL/FS point score = 10 x (0.8 x FL + 1.2 x FS) / Az) number of points (AHI = apnea-hypopnea index, FL = number of flow-limited breaths without snoring, FS = number of flow-limited breaths with snoring and Az = total number of breaths).

The form of the breathing flow curve is crucial in the detection of the flow limitation. The shape of the curve is based on that during inspiration, the breathing flow increases. After an amplitude peak is reached, the breathing curve flattens out

until expiration begins. In order to make a comparison between normal and flow-limited breathing, the two curves are superimposed. The area between the peak of the normal breathing flow and the flattened breathing curve of the flow-limited breathing, which is covered up only by the normal inspiration, indicates the missing breathing volume. To detect flow limitations, the ApneaLink algorithm compares the form of each detected breath with a number of predefined reference breaths. A blind independent observer of the PSG results performed the automatic analysis of ApneaLink™ with the version 5.26 software.

The RI cut off points that better discriminated between subjects with or without SAHS arose from the ROC curve analysis. Other positive ApneaLink™ criteria used in this study was an AHI = 5, 10 and 15 respectively.

We calculated the required sample size for the comparison of the area under a ROC curve (AUC) with a null hypothesis value (AUC = 0.5) (MedCalc Software, Version 9.2, Mariakerke, Belgium). We assumed a theoretical value of AUC of 0.9 according to a previous publication[16]. The alpha and beta error used was of 0.05 and 0.10 respectively. Thus, the minimal number of subjects was 38 (19 negative and positive subjects). To assess if the study variables had a normal distribution, we performed a frequency histogram and used the Kolmogorov-Smirnov test. Thus, when the distribution was normal, the mean and standard deviation were reported. Instead, the median and the 25-75% percentiles were used if the distribution was not normal. The Chi Square and the Mann Whitney test were used to evaluate significant differences between patients with mild, moderate and severe SAHS and between the AHI from ApneaLink™ and the RDI. The agreement between the measurements of ApneaLink (AHI, total number of apneas plus hypopneas) and the PSG (RDI, total number of apneas plus hypopneas) were assessed by the Bland and Altman plot. The ROC curve analysis was performed to assess which were the best RI cut-off points that identified subjects with or without SAHS. Similarly, for every definition of SAHS, we compared the area under the ROC curve of the best RI and AHI obtained from the ApneaLink™. Sensitivity, specificity, positive and negative likelihood ratio (PLR, NLR) were assessed for the different ApneaLink and SAHS criteria. The statistic analysis was carried out with commercially available software programme (MedCalc Software, Version 9.2, Mariakerke, Belgium).

TABLE 1.– *Patent characteristics*

Patient number	66
Age (years)*	51.5 ± 14.1
Men	47 (71%)
BMI (body mass index-kg/m^2)*	29.3 ± 5.4
Prevalence of SAHS (%)	
- RDI ≥ 5	77
- RDI ≥ 10	55
- RDI ≥ 15	47
Patients without SAHS (RDI < 5)	23
Severity of SAHS (%)	
- RDI ≥ 5 - < 15	30
- RDI ≥ 15 - < 30	21
- RDI ≥ 30	26
PSG	
- TRT (total recording time-min.)**	391.4 (387 - 398.3)
- TST (total sleep time-min.)*	310.7 ± 65.9
- TWT (total wakefulness time-min.)*	79.8 ± 62.6
- SE (sleep efficiency)*	0.79 ± 0.16
- TNREM (min.)*	257.7 ± 50.1
- TREM (min.)*	53.1 ± 30.1
- AHI (apnea/hypopnea index)**	9.5 (4.1 – 34.1)
- AI (apnea index)**	1.2 (0.15 - 11.9)
- HI (hypopnea index)**	6.1 (3.3 - 16.1)
- RDI (respiratory disturbance index)**	10.6 (5.4 - 34.1)

Values are expressed as the mean ± SD or the median and 25-75% percentiles***.
TNREM: total stages 1+2+3+4; TREM: total amount of REM sleep.

Results

Out of the 76 patients initially evaluated, one patient did not accept to participate in the study and 9 patients were ruled out due to several reasons (1 had a PSG with bad signal in one or more respiratory or neurophysiologic channels and 8 had an ApneaLink™ signal with frequent artefacts by nasal cannula disconnection and/or an evaluation period shorter than 4 h). Thus, 66 patients were included for the final analysis. The patient characteristics are shown in Table 1. The median evaluation period for the ApneaLink™ studies was of 377 minutes and the median total recording time for the PSG was 391 minutes. Men represented 71% of study sample. The prevalence of SAHS ranged from 47 to 77% depending on the cut-off point adopted to define SAHS. The proportion of subjects with mild, moderate and severe SAHS was similar (30%, 21% and 26% respectively, p 0.5). Seven patients with an AHI < 5 in the polysomnography were reclassified as slight SAHS when were included the RERA in the analysis (AHI 4.04 ± 1, RDI 8.8 ± 4.6, mean difference 4.7 ± 4.6, p < 0.034). The severity of SAHS evaluated by AHI was not modified by the addition of the RERA.

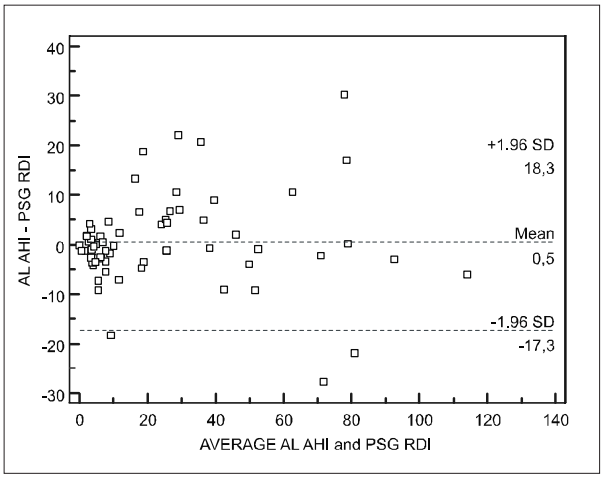

Fig. 1.– Bland-Altman plot of ApneaLink apnea-hypopnea index (AL AHI) and polysomnography respiratory disturbance index (PSG RDI) data.

A Bland-Altman plot of the data showed a reasonably tight distribution of the differences between the RDI from PSG and AHI from ApneaLink (Fig. 1). For RDI of 20 or less per hour the ApneaLink did not demonstrate any systematic bias. For RDI more than 20, the absolute discrepancy between ApneaLink and PSG widens, and there is a tendency for the ApneaLink to over or understate the AHI score. Since the valid total recording time of ApneaLink™ was higher than total sleep time (363.6 ± 38.6 min. versus 310.7 ± 65.9 min., $p < 0.01$) we would have expected that the AHI calculated by the ApneaLink™ should be less than RDI. However, the AHI measured by the ApneaLink™ was slightly higher than the RDI although it did not reach statistical significance (AHI 12, 25 - 75% percentiles 4 - 39, RDI 10.6 25-75% percentiles 5.4 - 34, p 0.72). This was because the automatic analysis of ApneaLink™ overestimated the number of respiratory events (apneas plus hypopneas) compared with the polysomnography. As shown in Fig. 2, the average difference between the number of apneas plus hipopneas of ApneaLink™ and the PSG was +32.8.

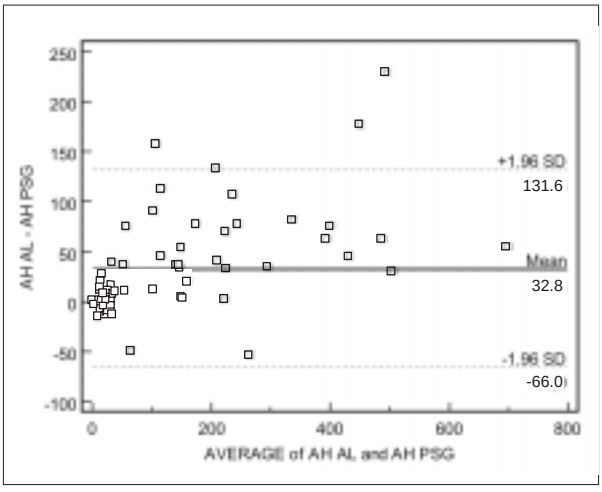

Fig. 2.– Bland Altman plot illustrating the agreement between the AH AL (number of apneas plus hypopneas of ApneaLink) and the AH PSG (number apneas plus hypopneas of the PSG).

The RI had the highest sensitivity and specificity at a value of 13 and 16 to diagnose SAHS defined as a RDI = 10 and 15 respectively (RI > 13: S = 92%, E = 93%; RI > 16: S = 93.5%, E = 91%). At a RDI ≥ 5, the RI had good specificity but a lower sensitivity, leading to a greater number of false negative results (Table 2). The AHI of ApneaLink™ showed the highest sensitivity and specificity at an AHI value of 15 or more events per hour (S = 93.5%, E = 91%) (Table 3). There was no difference between RI and AHI AUCs to detect SAHS at different levels of RDI from polysomnography (Table 4 and Fig. 3). The accuracy of ApneaLink was lower in subjects with mild SAHS and greater when the pathology was severe (Table 5). At lower RDI levels, the device had a lower sensitivity, leading to a greater number of false negative results.

Discussion

This study evaluated the diagnostic performance of the ApneaLink™ device and its automatic analysis software (version 5.26) in a group of patients that were referred to take a PSG due to SAHS suspicion. The novel finding of this study was that the risk indicator (RI), a combination of AHI plus inspiratory flow limitation events provided by the ApneaLink™ device, showed a high sensitivity and specificity in identifying patients with a RDI ≥ 15 obtained

TABLE 2.– *Sensitivity and specificity of risk indicator (RI) of ApneaLink™*

AL - PSG criteria	Sensitivity	95%CI	Specificity	95%CI	+LR	95%CI	-LR	95%CI	+PV	95%CI	-PV	95%CI
RI > 9 - RDI ≥ 5	80.4	66.9 - 91.4	100	78.0 - 100			0.20		100.0	91.3 - 100.0	60.0	38.7 - 78.8
RI > 13 - RDI ≥ 10	91.7	77.5 - 98.2	93.3	77.9 - 99.0	13.7	12.0 - 15.8	0.089	0.02 - 0.5	94.3	80.8 - 99.1	90.3	74.2 - 97.8
RI > 16 - RDI ≥ 15	93.5	78.5 - 99.0	91.4	76.9 - 98.1	10.9	9.5 - 12.5	0.071	0.01 - 0.4	90.6	75.0 - 97.9	94.1	80.3 - 99.1

95%CI: confidence interval 95%. +LR and -LR: positive and negative likelihood ratio. +PV and -PV: positive and negative predictive value.

TABLE 3.– *Sensitivity and specificity of apnea/hypopnea index (AHI) of ApneaLink™*

AL - PSG criteria	Sensitivity	95%CI	Specificity	95%CI	+LR	95%CI	-LR	95%CI	+PV	95%CI	-PV	95%CI
AHI ≥ 5-RDI ≥ 5	88.2	76.1 - 95.5	86.7	59.5 - 98.0	6.6	5.3 - 8.3	0.14	0.03 - 0.6	95.7	85.4 - 99.4	68.4	43.5 - 87.3
AHI ≥ 10-RDI ≥ 10	88.9	73.9 - 96.8	90.0	73.4 – 97.8	8.9	7.5 - 10.5	0.12	0.03 - 0.5	91.4	76.9 - 98.1	87.1	70.1 - 96.3
AHI ≥ 15-RDI ≥ 15	93.5	78.5 - 99.0	91.4	76.9 - 98.1	10.9	9.5 - 12.5	0.071	0.01 - 0.4	90.6	75.0 - 97.9	94.1	80.3 - 99.1

95%CI: confidence interval 95%. +LR and -LR: positive and negative likelihood ratio. +PV and -PV: positive and negative predictive value.

TABLE 4.– *Comparison between RI and AHI AUCs*

	RI		AHI		
	AUC	95%CI	AUC	95%CI	p
PSG criterion = RDI ≥ 5					
AL criterion: RI > 9 vs. AHI ≥ 5	0.90	0.80 – 0.96	0.875	0.77 - 0.94	0.53
PSG criterion = RDI ≥ 10					
AL criterion: RI > 13 vs. AHI ≥ 10	0.92	0.83 – 0.97	0.89	0.79 - 0.96	0.52
PSG criterion = RDI ≥ 15					
AL criterion: RI > 16 vs. AHI ≥ 15	0.95	0.87 – 0.99	0.925	0.83 - 0.975	0.42

AUCs: areas under the ROC curve. 95%CI: confidence interval 95%. RI: risk indicator. AHI: apnea/hypopnea index. RDI: respiratory disturbance index. AL: ApneaLink.

TABLE 5.– *Sensitivity and specificity of apnea/hypopnea index (AHI) of ApneaLink™ according to the severity of SAHS*

PSG criteria	Sensitivity	95%CI	Specificity	95%CI	+LR	95%CI	-LR	95%CI	+PV	95%CI	-PV	95%CI
RDI ≥ 5 - < 15	75.0	51 - 91.3	86.7	59.5 - 98.3	5.6	4.1 - 7.8	0.29	0.06 - 1.3	88.2	63.6 - 98.5	72.2	46.5 - 90.3
RDI ≥ 15 - < 30	85.7	57.2 - 98.2	91.4	76.9 - 98.2	10	7.9 - 12.7	0.16	0.03 - 0.8	80	51.9 - 95.7	94.1	80.3 - 99.3
RDI ≥ 30	100	80.5 - 100	89.8	77.8 - 96.6	9.8	8.9 - 10.8	0.00	–	77.3	54.6 - 92.2	100	92 - 100

95%CI: confidence interval 95%. +LR and -LR: positive and negative likelihood ratio. +PV and -PV: positive and negative predictive value.

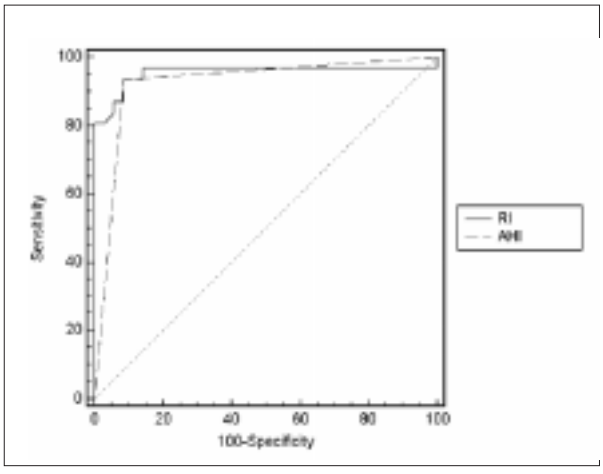

Fig. 3.– Comparison between RI and AHI area under the curves ROC (SAHS = RDI ≥ 15)

from full PSG. Thus, a RI ≤ 16 had a sensitivity of 93.5% and a negative likelihood ratio lower than 0.07 to exclude moderate to severe pathology defined as a RDI ≥ 15 by PSG. On the other hand, a RI > 16 had a specificity of 91% and a positive likelihood ratio of 11 to confirm the presence of SAHS defined as RDI ≥ 15. Similarly, the AHI obtained from ApneaLink™ device showed similar diagnostic accuracy to RI to correctly classify patients with SAHS defined as a RDI ≥ 15. These results are consistent with previous studies that demonstrated good sensitivity and specificity for the ApneaLink™ or similar devices at an AHI ≥ 10 or 15, when compared with an AHI from PSG in populations referred to as a sleep laboratory for the assessment of sleep apnea [14-16]. However, none of these studies analysed the accuracy of risk indicator, a parameter that includes the inspiratory flow limitation breathe in addition of AHI to identify the SAHS. Wang et al[14] compared the micro-MESAM automated analysis with manually scored results of simultaneously collected PSG in 50 patients suspected of having obstructive sleep apnea. For SAHS defined as an AHI ≥ 5 and 10, the sensitivity and specificity were 97% / 45% and 100% / 89% respectively. Like us, the micro-MESAM overestimated the number of hypopneas and the AHI respect to the polysomnography (mean difference + 28 and + 3.8 respectively). Grover et al[15] studied 25 patients with a single channel portable monitoring device that measures nasal pressures (a surrogate for airflow) to detect sleep disordered breathing (SDB) concurrently with standard polysomnography in the sleep laboratory. The portable device automatically calculated a respiratory events index (REI) based on recording time. For a REI > 11.9 events per hour, the sensitivity was 89% and the specificity was 86% to diagnostic SDB defined as an AHI ≥ 5. Similar results were observed for detecting moderate-severe SDB (AHI ≥ 15) using a REI > 15.2. Finally, Erman et al[16] studied 59 patients with type 2 diabetes. They compared the AHI from the ApneaLink™ device to that obtained during simultaneously conducted attended sleep-laboratory PSG. They also compared the AHI from ApneaLink™

TABLE 6.– Comparison between the present study and previous publications

	Nigro et al	Erman et al[16]	Wang et al[14]	Grover et al[15]
Patients (n)	66	53	50	25
Study site	SL	SL / H	SL	SL
Device	ApneaLink	ApneaLink	MicroMESAM	RUSleepingtrade
Software	V 5.26	V 5.13		
	–	–	–	REI > 11.9
				REI > 15.2
Positive ApneaLink	RI > 9			
	RI > 13			
	RI > 16			
	AHI ≥ 5	AHI ≥ 5	AHI ≥ 5	–
	AHI ≥ 10	AHI ≥ 10	AHI ≥ 10	
	AHI ≥ 15	AHI ≥ 15		
Definition of SAHS	RDI ≥ 5	AHI ≥ 5		
from PSG	RDI ≥ 10	AHI ≥ 10	AHI ≥ 5	AHI ≥ 5
	RDI ≥ 15	AHI ≥ 15	AHI ≥ 10	AHI ≥ 15
	AHI ≥ 5			
Sensitivity (%)	RI > 9 / RDI ≥ 5: 80			
	RI > 13 / RDI ≥ 10: 92	–	–	–
	RI > 16 / RDI ≥ 15: 93.5			
	AHI ≥ 5 / RDI ≥ 5: 88	AHI ≥ 5 / AHI ≥ 5: 85.4	AHI ≥ 5 / AHI ≥ 5: 97	REI ≥ 11.9 / AHI ≥ 5: 89
	AHI ≥ 10 / RDI ≥ 10: 89	AHI ≥ 10 / AHI ≥ 10: 82.1	AHI ≥ 10 / AHI ≥ 10: 100	AHI ≥ 15.2 / AHI ≥ 15: 89
	AHI ≥ 15 / RDI ≥ 15: 93.5	AHI ≥ 15 / AHI ≥ 15: 91		
Specificity (%)	RI > 9 / RDI ≥ 5: 100			
	RI > 13 / RDI ≥ 10: 93	–	–	–
	RI > 16 / RDI ≥ 15: 91			
	AHI ≥ 5 / RDI ≥ 5: 87	AHI ≥ 5 / AHI ≥ 5: 50	AHI ≥ 5 / AHI ≥ 5: 46	REI ≥ 11.9 / AHI ≥ 5: 86
	AHI ≥ 10 / RDI ≥ 10: 90	AHI ≥ 10 / AHI ≥ 10: 84	AHI ≥ 10 / AHI ≥ 10: 87.5	AHI ≥ 15.2 / AHI ≥ 15: 86
	AHI ≥ 15 / RDI ≥ 15: 91	AHI ≥ 15 / AHI ≥ 15: 95		

SL: sleep laboratory. H: home. RI: risk indicator. AHI: apnea/hypopnea index. RDI: respiratory disturbance index. REI: respiratory events index

during a study in the subjects' homes to that obtained during the in-laboratory study. The best result in sleep laboratory was obtained at an AHI ≥ 15 (sensitivity 91%, specificity 95%). The AHI comparison from the home and laboratory studies demonstrated a sensitivity of 76% and a specificity of 94% at AHI level of ≥ 15. The comparison between previous publications and this study is shown in Table 6.

In those patients with high clinical probability of moderate to severe SAHS, a prompt access to the PSG should be guaranteed by the health care system. However, the waiting time estimated for performing a PSG has ranged in several countries from 2 to 60 months[23]. In this context, the availability of a simple, portable and validated technology as the ApneaLink™ device would allow decision making on patients referred for suspicion of SAHS. In addition, the automatic analysis avoids the experienced observer's bias in the interpretation, making the method is reliable and reproducible. However, the sensitivity of ApneaLink™ device in patients with milder form of SAHS was lower than subjects with severe SAHS (75% vs. 100%). Therefore, the patients with suspected SAHS and a negative study, it should be performed a PSG to confirm SAHS.

This study had some limitations. First, we used thermistors and thoracoabdominal bands to score the hypopneas. Both methods can underestimate the number of hypopneas when compared with nasal pressure[24, 25]. When the capabilities of a new diagnostic test are evaluated by making reference to an imperfect standard, biases are introduced into measures of test performance[26]. In order to minimize biases as result of our imperfect standard, we decided to score the RERA by a validated noninvasive method[19]. Thus, 7 patients with an AHI < 5 were reclassified as SAHS by RDI. In this way, the effect of misclassification could be reduced by using a particularly rigorous definition of disease[26]. Besides, we did not use a predetermined descent in the respiratory signals (thermistors, thoracic and abdominal bands) for the identification of hypopneas. Therefore, any fall in the respira-

tory signals plus oxygen desaturation and/or associated arousal was classified as hypopnea. Thus, we avoided to sub-estimate the number of hypopneas and consequently the respiratory disturbance index. In fact, we observed a similar test performance to that of previous publications which compared ApneaLink™ or similar devices with nasal pressure in the polysomnography (see Table 6). The second limitation is the applicability of these results at home. Due to the design of this study, we can not draw valid conclusions about the accuracy of the ApneaLink™ device to detect or exclude SAHS outside the sleep laboratory without technical control. Thirdly, the hereby reported cut off points of RI for screening or diagnosing SAHS should be taken cautiously since SAHS prevalence in general population is lower than in our study sample, which could reduce the diagnosis capacity of ApneaLink™ device[27].

This study demonstrated that the ApneaLink™ device provides reliable information, it is a simple, easy-to-use device, and the RI and AHI automatically obtained were highly sensitive and specific to diagnostic moderate to severe SAHS. However, other studies are necessary to know if the results found in our study are applied at home and in populations with low prevalence of SAHS.

Conflicts of interest: We declare that there were no conflicts of interest related to this investigation.

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