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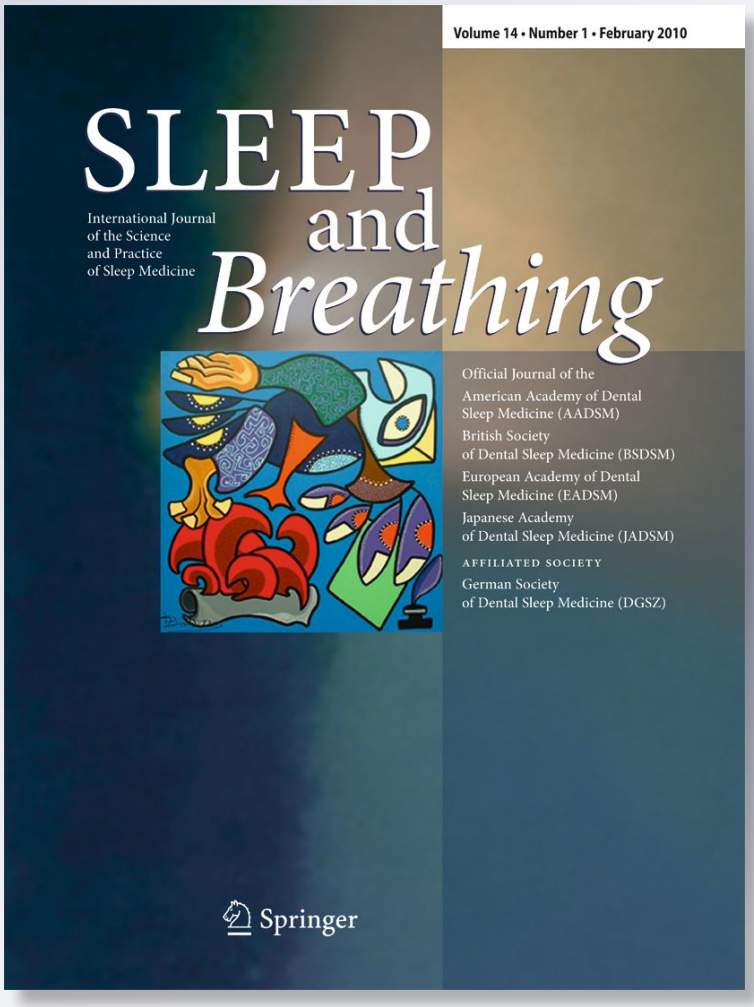

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ORIGINAL ARTICLE

Validation of ApneaLink Ox™ for the diagnosis of obstructive sleep apnea

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Abstract
Objective The aim of the study was to validate the automatic and manual analysis of ApneaLink Ox™ (ALOX) in patients with suspected obstructive sleep apnea (OSA).
Methods All patients with suspected OSA had a polysomnography (PSG) and an ALOX performed in the sleep laboratory. For automatic analysis, hypopnea was defined as a decrease in airflow ≥30 % of baseline for at least 10 s plus oxygen desaturation ≥3 or 4 %. While for the manual analysis, hypopnoea was considered when a reduction of airflow ≥30 % of ≥10 s plus oxygen desaturation ≥3 % or increase in cardiac rate ≥5 beats/min were identified or, when only a reduction of airflow ≥50 % was observed. OSA was defined as a respiratory disturbance index (RDI) ≥5. The apnea/hypopnea automatic index (AHI3-a, AHI4-a) and manual index were estimated. Receiver operating characteristics (ROC) analysis and the agreement between ALOX and PSG were performed.
Results Fifty-five patients were included (38 men; mean age, 48.2; median, RDI 15.1; median BMI, 30 Kg/m^2). The automatic analysis of ALOX under-estimated the RDI from PSG, mainly for the criterion of oxygen desaturation ≥4 % (AHI3-a–RDI, −3.6±10.1; AHI4-a–RDI, −6.5±10.9, $p<0.05$). The autoscoring from ALOX device showed a better performance when it was set up to identify hypopneas with an oxygen desaturation criterion of ≥3 % than when it was configured with an oxygen desaturation criterion of ≥4 % (area under the receiver operator curves, 0.87 vs. 0.84). Also, the manual analysis was found to be better than the autoscoring set up with an oxygen desaturation of ≥3 % (0.923 vs. 0.87). The manual analysis showed a good interobserver agreement for the classification of patients with or without OSA (k=0.81).
Conclusion The AHI obtained automatically from the ApneaLink Ox™ using oxygen desaturation ≥3 % as a criterion of hypopnea had a good performance to diagnose OSA. The manual scoring from ApneaLink Ox™ was better than the automatic scoring to discriminate patients with OSA.

Keywords Portable sleep monitoring · Obstructive sleep apnea · Sleep apnea syndromes · Diagnosis

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Introduction

In Western populations, the prevalence of obstructive sleep apnea (OSA; defined as greater than 15 obstructed breathing events per hour of sleep) was around 7 % in the 1990s [1]. Studies suggest that OSA may be equally common in China and other Asian countries [2–4] and that it is increasing in prevalence in line with the current global epidemic of obesity [5]. OSA causes daytime sleepiness, increased traffic accidents, impaired quality of life and significant cardiovascular

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morbidity and mortality [6–8]. Given the huge impact of OSA on the health of people, it is essential to quickly detect those patients with symptoms suggestive of sleep apnea. The gold standard for diagnosing OSA is polysomnography performed in the sleep laboratory [9]. However, this methodology requires an appropriate place (sleep laboratory) and highly qualified personnel for conducting and interpreting the results. For these reasons, this technology is not always easily accessible. In fact, the delay to perform a polysomnography may be up to 6 months in some countries [10]. Owing to the cost, the requirement for technical expertise and the accessibility to diagnosis, a number of alternatives to polysomnography (PSG) have been proposed [11].

Up to date, several studies have evaluated the performance of a single airflow channel recording (ApneaLink™) device to detect sleep-related breathing disorders in patients with suspicion of obstructive sleep apnea [12–17] or Cheyne Stokes respiration [18]. The results demonstrated good sensitivity and specificity of apnea/hypopnea index (AHI) obtained from this equipment 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 Ox™ is a two-channel screening tool for sleep apnea. The device consists of a nasal cannula attached to a small case that houses a pressure transducer and a pulse oximeter. The device is held in place by a belt worn around the user's chest. It has good potential as a simple screening device, particularly because it permits manual review and scoring of the raw data. Only three studies have evaluated the ApneaLink Ox™ for diagnosing patients with suspected OSA. However, in these studies, either the authors assessed only the automatic analysis of the airflow signal to identify hypopneas without taking into account oxygen desaturation [19, 20] or the study was designed to evaluate the prevalence of OSA in patients with acute coronary syndrome [21]. Thus, the primary objective of this study was to validate the automatic and manual analysis of ApneaLink Ox™ in a population of patients with suspected OSA.

Methods

Patient selection

A prospective clinical study was performed in 60 consecutive patients referred to the Hospital Alemán and the Instituto Argentino de Investigación Neurológica for possible OSA. The recruitment period extended from July 2010 to January 2011. The selection criteria were the following:

– *Inclusion criteria*

1. OSA-suspected patients of both sexes (snoring with/without other symptoms such as apneas referred by someone and/or somnolence)
2. Age equal to or over 18 years old
3. Informed consent

– *Exclusion criteria*

1. Use of oxygen, continuous positive airway pressure or some modality of non-invasive mechanical respiratory assistance during PSG
2. Age under 18 years old
3. Polysomnographies with artefacts in EEG or respiratory channels (airflow, thoraco-abdominal movements and SO_2) that do not allow the reading of the sleep stages or the respiratory events
4. ApneaLink Ox™ with less than 2 or 4 h of automatic or manual evaluation period, respectively

All the patients had PSG and an ApneaLink Ox™ performed simultaneously in the sleep laboratory.

Measurements

(a) *Polysomnography*

All the patients underwent overnight polysomnography with a computerised polysomnographic system (Mini PC, Akonic, Buenos Aires, Argentina or Harmonie, Stellate Systems, Canada; F4/A1, C4/A1, and O2/A1), bilateral electrooculogram, submental electromyogram, bilateral leg electromyogram, and electrocardiogram. Airflow was measured by nasal pressure and oral thermistor; respiratory effort was assessed by a thoraco-abdominal piezoelectric belt and oxygen saturation (SO_2) was recorded using a finger probe (Nonin, Plymouth, MN, USA). The polysomnographies were registered from 10:30–11:30 PM to 05–06 AM. On the day of the study, the patients were given the following instructions: (1) to avoid napping and not to drink alcohol or beverages with caffeine (coffee, tea and cola drinks); (2) to continue the usual medication; (3) to eat supper between 8:30 and 9:30 PM; (4) to report to the sleep laboratory between 10:30 and 11:30 PM.

– *PSG analysis*

PSG reading was performed manually by two widely-experienced medical staff members who were blind to the operator that analysed the ApneaLink Ox™. The sleep stages were analysed in 30-s epochs according to international criteria [22]. The arousals were identified following the American Sleep Disorder Association recommendations [23]. The analysis of apneas, hypopneas and respiratory effort-related arousals (RERAs) were in agreement with the international criteria [24, 25]. The following definitions were used:

- Respiratory disturbance index (RDI): number of apneas plus hypopneas plus RERAs per hour of sleep [26].
- OSA was defined as an RDI ≥5.

- Severity of OSA: mild=RDI ≥5 to <15; moderate= RDI ≥15 to <30; severe RDI ≥30 [27].

(b) *ApneaLink Ox™*

The ApneaLink Ox™ was used to compare its diagnosis accuracy with respect to PSG. ApneaLink Ox™ records patient respiratory nasal pressure and blood oxygen saturation during sleep. 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 [28]. The blood oxygen saturation and pulse rate are measured using the finger pulse sensor and the pulse oximeter (XPod, Nonin). The XPod module has motion-tolerant software that minimises the likelihood of motion artefact being misinterpreted as good pulse quality.The ApneaLink Ox™ device operates on battery power, has a sampling rate of 100 Hz (airflow), 1 Hz (oxygen saturation) and a 20-bit signal processor. The internal memory storage is 15 MB, which allows for approximately 10 h of data collection.

During the night of laboratory evaluation, subjects also wear an ApneaLink Ox™ device. The nasal cannula used by the patients during the study is attached to a "T" connector leading to a pressure transducer, allowing for the simultaneous recording of the flow signal by the ApneaLink Ox™ device and the PSG system.

– *ApneaLink Ox™ analysis*

A blind independent observer of the PSG results performed the automatic analysis of ApneaLink Ox™ by a computer program (version 9). The ApneaLink Ox™ default setting for apnea was used in this study. An apnea was defined as a decrease in airflow by 80 % of baseline for at least 10 s. The ApneaLink Ox™ default maximum apnea duration was set at 80 s. A hypopnea was defined in two ways: decrease in airflow ≥30 % of baseline for at least 10 s plus oxygen desaturation ≥3 or 4 %. The ApneaLink Ox™ default maximum hypopnea duration was set at 100 s. The apnea/hypopnea index for each definition of hypopnea was calculated as the number of apneas/hypopneas per hour of automatic evaluation period (AHI3-a, AHI4-a). To avoid the bias introduced by the automatic analysis on manual scoring, we deleted the autoscoring and then, a blind independent observer of the results of the automatic analysis performed the manual analysis of the signals from the ApneaLink Ox™. If required, the operator could include or exclude sectors of the recording for their analysis. Apnea was defined as the absence of airflow lasting ≥10 s. Hypopnea was considered when a reduction of airflow ≥30 % of baseline ≥10 s plus oxygen desaturation ≥3 % or evidence of autonomic arousal were identified at the end of hypopneas or when only a reduction of airflow ≥50 % was observed. We use as criterion for autonomic arousal an increase in the pulse rate of at least 5 beats per minute, although this is mostly accurate during non-rapid eye movement sleep [29, 30]. The manual apnea/hypopnea was calculated as the number of apneas/hypopneas per hour of evaluation period (AHI-m). The positive ApneaLink Ox™ criteria used in this study was an AHI ≥5.

Statistical analysis

To assess if the study variables had a normal distribution, a frequency histogram and the Kolmogorov–Smirnov test were performed. Thus, when the distribution was normal, the mean and standard deviation were reported. Instead, the median and the percentiles 25–75 % were used if the distribution was not normal. The McNemar test was used to evaluate significant differences between patients with mild versus moderate to severe OSA and between sensitivity and specificity of the automatic and manual analysis from the ApneaLink Ox™ device. To measure the overall agreement between the RDI and the AHI of the ApneaLink Ox™, we calculated the intraclass correlation coefficient (ICC). The ICC values were interpreted according to the classification proposed by Pita Fernandez et al. [31]. The nature and extent of the disagreement between the RDI and the AHI from ApneaLink Ox™ was assessed by Bland and Altman plot. The degree of association among the variables (AHI-a/AHI-m, RDI) was evaluated by the Spearman's rho rank correlation coefficient. The diagnostic accuracy of the automatic and manual analyses of the ApneaLink Ox™ with the different definitions of OSA was assessed using the receiver operating characteristics (ROC) curve. Sensitivity, specificity as well as positive and negative likelihood ratio (PLR, NLR) were calculated. The inter-observer agreement of manual scoring of the ApneaLink Ox™ was assessed in a subgroup of 15 patients selected at random through kappa statistics. Statistical analysis was carried out with a commercially available software programme (MedCalc Software, Version 11.6, Mariakerke, Belgium). Sensitivity and specificity from previous studies were pooled by a computer programme (Meta-DiSc version 1.4, Universidad Complutense, Madrid, Spain).

Results

Out of the 60 patients initially evaluated, two patients did not accept to participate in the study and three patients were ruled out due to several reasons (one had a total sleep time by PSG less than 180 min, two had an ApneaLink™ Ox signal with frequent artefacts due to finger clip probe disconnections and/or an automatic evaluation period shorter than 1 h.). Thus, 55 patients were included in the final analysis.

Table 1 Patient characteristics

Patient number	55
Age (years)[a]	48.2±14.5
Men	38 (69)
BMI (body mass index, kg/m^2)[a]	30±7.2
Prevalence of OSA (%)	
RDI ≥5	43 (78.2)
Severity of OSA (%)	
RDI ≥5 to <15	15 (27.3)
RDI ≥15 to <30	13 (23.6)
RDI ≥30	15 (27.3)
PSG	
Total recording time (TRT, min)[a]	369.3±22.8
Total sleep time (TST, min)[a]	313.6±40
Total wakefulness time (TWT, min)[a]	55.7±42
Sleep efficiency (SE)[a]	0.85±0.11
TNREM (min)[a]	274±42
TREM (min)[a]	39.1±27.8
Respiratory disturbance index (RDI)[b]	15.1 (6.3 - 34.6)
Comorbidities	
Hypertension	24 (44)
Coronary heart disease	5 (9)
Cerebrovascular ischemia	2 (3.6)
Arrhythmia	6 (11)
Asthma	2 (3.6)
Allergic rhinitis	15 (27.3)

OSA obstructive sleep apnea, *TNREM* total stages 1+2+3+4; *TREM* total amount of REM sleep

[a] Data are presented as mean±SD

[b] Median (25–75 % percentiles) or *n* (%)

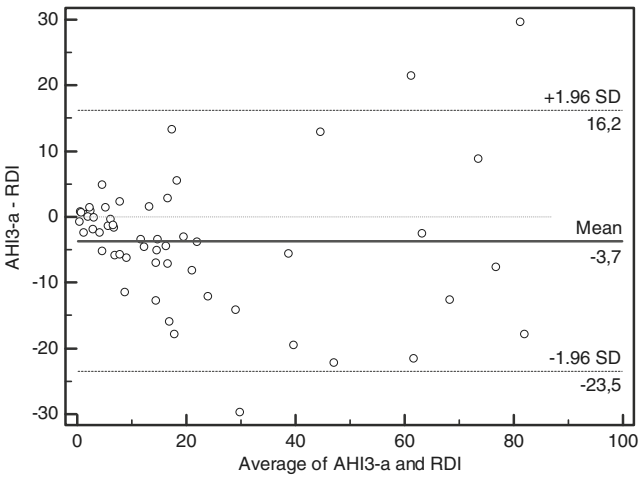

Fig. 1 Bland–Altman plot of automatic ApneaLink Ox apnea/hypopnea index (criterion hypopnea: oxygen desaturation ≥3 %; AHI3-a) and the respiratory disturbance index (RDI) from PSG

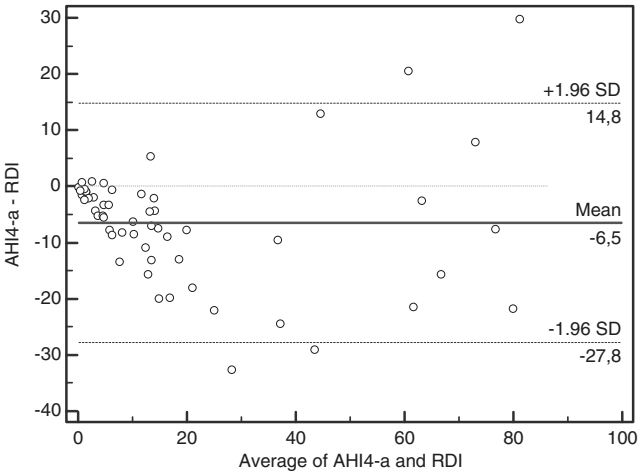

Fig. 2 Bland–Altman plot of automatic ApneaLink Ox apnea/hypopnea index (criterion hypopnea: oxygen desaturation ≥4 %; AHI4-a) and the respiratory disturbance index (RDI) from PSG

Subjects characteristics

The patient characteristics are shown in Table 1. The evaluation period of the automatic scoring was lower than its manual counterpart (319.7±66.3 vs. 342.6±30.1 min, p=0.022). The mean total recording time for the PSG was 369.3 min. Men represented 69 % of the study sample. The prevalence of OSA was of 78 %. The proportion of mild (27.3 %), moderate (23.6 %), and severe OSA (27.3 %) was similar (p=0.93).

Agreement between ApneaLink Ox™ and PSG

The strength of agreement between the AHI from ApneaLink Ox™ with both criteria of hypopnea and the RDI was good

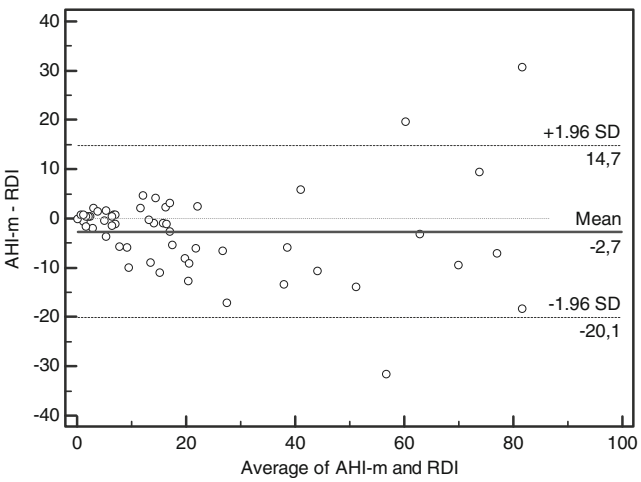

Fig. 3 Bland–Altman plot of manual ApneaLink Ox apnea/hypopnea index (AHI-m) and the respiratory disturbance index (RDI) from PSG

Table 2 Comparison of ROC curves from ApneaLink Ox™

Criterion OSA	Automatic		Manual
ALOX (AHI)/ PSG (RDI)	Hyponea criterion OD3 AUC-ROC (SE)	Hyponea criterion OD4 AUC-ROC (SE)	AUC-ROC (SE)
≥5/≥5	0.87 (0.06)	0.84 (0.05)	0.923 (0.05)

ALOX ApneaLink Ox™, *OD3/4* oxygen desaturation 3 or 4 %, *AUC-ROC* area under the ROC curve (standard error)

for the automatic analysis (AHI3-a/AHI4-a versus RDI: ICC 0.87–0.90) and very good for the manual analysis of the ApneaLink Ox™ (AHI-m/RDI: ICC 0.93). The automatic analysis of ApneaLink Ox™ showed a tendency to underestimate the RDI from PSG, mainly for the criterion of oxygen desaturation ≥4 % (mean difference AHI3-a–RDI, −3.6±10.1; mean difference AHI4-a–RDI, −6.5±10.9; $p<0.05$; Figs. 1 and 2). The average differences between the AHI3-a, the AHI4-a and the RDI were −1.2±4.4 and −3.7±3.9, respectively, for mild OSA ($p<0.05$) and −7.3±14.5 and −10.6±5.8, respectively, for moderate to severe OSA ($p<0.05$). The mean difference between the manual scoring from ApneaLink Ox™ (AHI-m) and the PSG (RDI) was −2.7±8.9 (Fig. 3). For RDI values less than 15, the absolute discrepancy between the manual analysis of the ApneaLink Ox™ and the PSG was lower than for RDI values of 15 or more (−0.6±3 vs. −4.7±11.8, $p<0.05$).

Accuracy of automatic and manual scoring from ApneaLink Ox

Table 2 summarises the values of the area under the receiver operator curves (AUC-ROCs) for the automatic and manual ApneaLink Ox™ scores. The best area under the ROC curve was observed with the hand scoring. The automated analysis carried out using oxygen desaturation ≥3 % as a criterion for hypopnea was better than its counterpart with 4 %. The results comparing sensitivity and specificity of automatic versus manual AHI gained from the ApneaLink Ox™ device against the RDI from the PSG are shown in Table 3. The autoscoring from ApneaLink Ox™ device showed a better performance when it was set up to identify hypopneas with an oxygen desaturation criterion of ≥3 % than when it was configured with an oxygen desaturation criterion of ≥4 %. Also, the manual analysis was found to be better than the autoscoring set up with an oxygen desaturation of ≥4 %. The manual analysis of ApneaLink Ox™ classified the presence of OSA correctly in more than 90 % of the patients. There were three false-negative (FN) and one false-positive (FP) cases. FN cases had mild disease (RDI ≥5 to <15). The FP subject was one man with an AHI-m of 6.1 and an RDI of 4.5. The manual analysis showed a very good inter-observer agreement for the classification of patients with or without OSA ($k=0.81$).

Discussion

We assessed the diagnostic performance of the ApneaLink Ox™ system and its automatic analysis software (version 9.00) using different hypopnea criteria and compared the autoscoring versus the manual analysis in a group of patients that were referred to take a PSG due to OSA suspicion. The ApneaLink Ox incorporates pulse oximetry to the airflow signal, which allows the identification of hypopneas with more precision since it detects not only the fall of the SO_2 but also the increase in heart rate toward the end of the hypopnea indicating the presence of an arousal [29, 30]. Our study demonstrated that the diagnostic

Table 3 Accuracy of the automatic and manual analysis from ApneaLink OX™ (criteria OSA AHI-a/RDI ≥5)

Automatic analysis ALOX™								Manual analysis ALOX™			
Hypopnea criterion											
Oxygen desaturation, ≥3 %				Oxygen desaturation, ≥4 %							
Sensitivity (95 %CI)	Specificity (95 %CI)	−LR	+LR	Sensitivity (95 %CI)	Specificity (95 %CI)	−LR	+LR	Sensitivity (95 %CI)	Specificity (95 %CI)	−LR	+LR
90.70* (77.9–97.4)	83.3* (51.6–97.9)	0.11	5.4	76.7* (61.4–88.2)	91.7* (61.5–99.8)	0.25	9.2	93** (80.9–98.5)	91.7** (61.5–99.8)	0.08	11.6

ALOX™ ApneaLink Ox™, *AHI-a* automatic apnea/hypopnea index from ALOX, *RDI* respiratory disturbance index (PSG), *CI95 %* 95 % confidence interval, *−LR/+LR* negative and positive likelihood ratio

*$p<0.05$, significant difference between sensitivity and specificity from automatic analysis

**$p<0.05$, significant difference between automatic (oxygen desaturation 4 %) and manual analysis

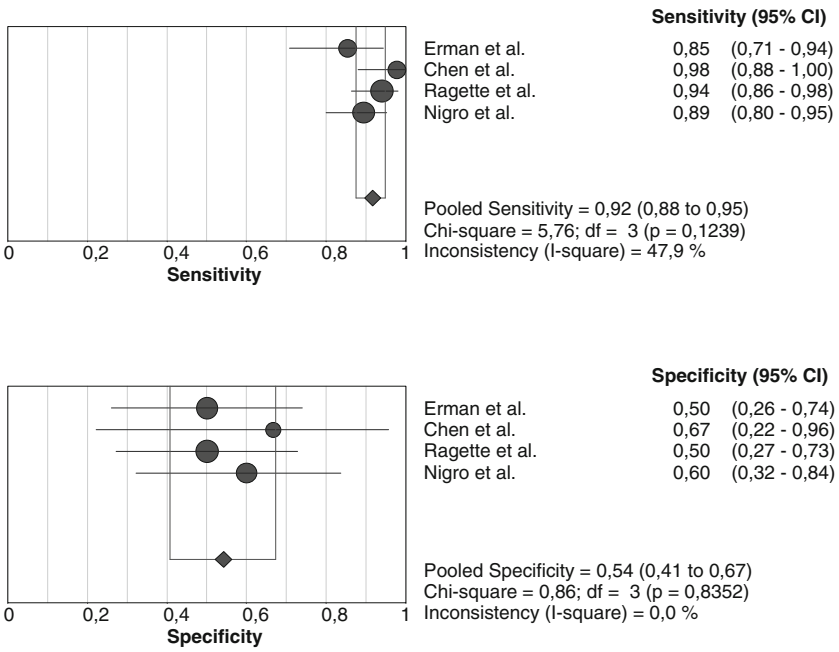

Fig. 4 ApneaLink device versus polysomnography, automatic scoring (OSA criteria: AHI-a/RDI ≥5)

performance of the autoscoring of data using the recommended criteria of the AASM (↓ airflow ≥30 % plus oxygen desaturation ≥4 %) to define hypopneas was lower than the automated scoring provided by the ApneaLink Ox device configured with an oxygen desaturation ≥3 % as a hypopnea criterion. The previous validation studies of the ApneaLink device without oximetry against polysomnography that used the automatic analysis through a program [12–15] showed a pooled sensitivity of 92 % (95 % CI, 87.5–95) and a pooled specificity of 54 % (95 % CI, 41–67.3) without heterogeneity between the studies ($p>0.05$) (see Fig. 4). The automatic system identified most patients with OSA, but specificity was low due to a high proportion of false-positive results in all the studies. The addition of the oximetry has improved the performance of the automatic analysis from the ApneaLink Ox™ to diagnose OSA primarily due to an increase in specificity. The improvement in the diagnostic accuracy of autoscoring from ApneaLink Ox™ was observed mainly when the criterion used to identify hypopneas was an oxygen desaturation ≥3 % (see Table 4). Also, we observed that the hand scoring showed to be superior to the autoscoring of the ApneaLink Ox. These results are consistent with previous studies. We have recently demonstrated [15] that the manual analysis of data using an AHI (ApneaLink ™) and an RDI (PSG) ≥5 as criteria for OSA has improved diagnostic accuracy of autoscoring usually due to an increase in specificity. Koziej et al. [32] compared the Mesam 4™, a portable device with four-channel digital recording (SO_2, heart rate, snoring sounds, body position), against polysomnography in the sleep laboratory. They showed that the sensitivity and specificity of hand scored Mesam 4™ for the diagnosis of OSA (AHI ≥10) were 100 and 63 %, respectively, while the sensitivity and specificity with the automatic scoring (oxygen desaturation index) were 100 and 27 %, respectively. Also, Esnaola et al.

Table 4 Accuracy of automatic analysis from ApneaLink OX™ and ApneaLink™ (criteria OSA AHI-a/RDI ≥5)

Automatic analysis ApneaLink OX™				Automatic analysis ApneaLink™	
Hypopnea criterion				Hypopnea criterion (↓ airflow, ≥50 %)	
Oxygen desaturation, ≥3 %		Oxygen desaturation, ≥4 %			
Sensitivity (95 %CI)	Specificity (95 %CI)	Sensitivity (95 %CI)	Specificity (95 %CI)	Pooled sensitivity (95 %CI)	Pooled specificity (95 %CI)
90.7 (77.9–97.4)	83.3* (51.6–97.9)	76.7** (61.4–88.2)	91.7 (61.5–99.8)	91.7** (87.5–94–9)	54.2* (40.8–67.3)

AHI-a automatic apnea/hypopnea index from ApneaLink, *RDI* respiratory disturbance index (PSG), *CI95 %* 95 % confidence interval

*$p=0.04$, significant difference between specificity from automatic analysis

**$p=0.002$, significant difference between sensitivity from autoscoring

[33] compared the manual versus the automated scoring of the Mesam 4™ to detect OSA (AHI ≥5). The manual scoring (MS) was also better than the automatic scoring (AS; AUC-ROC MS, 0.89–0.91 versus AUC-ROC AS, 0.71–0.74). Calleja et al. [34] observed that the manual score of the Merlin™ system, a cardiorespiratory polygraph level 3 (airflow by thermistor, respiratory movements, SO_2, cardiac frequency, body position) was more accurate than the automatic scoring to identify OSA-suspected patients (AHI ≥5) (sensitivity/specificity, manual scores 97.1/90.9 % and automatic scores 82.3/63.6 %). Finally, Dingli et al. [35] evaluated the Embletta™ respiratory polygraph versus the PSG to diagnose OSA (AHI ≥10). The sensitivity with the manual and automatic scorings was similar with both methods (87 %) but the specificity increased from 33 to 100 % with the manual scoring.

This study had some limitations. The first is the applicability of these results at home. Due to the design of this study, we cannot draw valid conclusions about the accuracy of the ApneaLink Ox device to detect or exclude OSA outside the sleep laboratory without technical control. Secondly, the ApneaLink fails to distinguish between central and obstructive apnea because the recordings are based only on airflow, limiting its value in patients with suspected central sleep apnea. Thirdly, because it is impossible to estimate the total sleep time from the ApneaLink, its value is limited in patients who report sleeping less on the night of the exam. Finally, the small number of patients enrolled in this study, especially the limited number of subjects without sleep apnea, could have potentially over-estimated the performance of the ApneaLink Ox to diagnose OSA.

In summary, this study demonstrated that the ApneaLink Ox™ device provides reliable information, it is a simple, easy-to-use device, and the AHI automatically obtained using an oxygen desaturation of ≥3 % as criterion of hypopnea were highly sensitive and specific to diagnose OSA. On the other hand, the manual scoring of an ApneaLink Ox™ recording applied in the sleep laboratory by an experienced sleep physician was a reliable procedure indicated by the good inter-observer agreement and better than the automatic scoring in terms of agreement with RDI and to discriminate patients with OSA. Thus, more than 90 % of the patients were correctly classified. Further studies should assess the diagnostic accuracy of the ApneaLink Ox™ system in an unattended setting in non-referral populations.

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