

## Evaluation of a portable respiratory recording device for detecting apnoeas and hypopnoeas in subjects from a general population

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**ABSTRACT:** This study was designed to validate a new home portable respiratory recording device (PRRD) to identify sleep apnoea and hypopnoea in a group of subjects (n=116), from a sample of the general population.

Full night polysomnography (PSG) was used as the gold standard and simultaneously performed with PRRD. PRRD measurements included oronasal airflow (thermistry), chest wall impedance, oxygen saturation, snoring and body position. The sensors were unique for each recording system. Data obtained was blindly reviewed and analysed.

A high level of agreement between both methods apnoea/hypopnoea index by PSG and the respiratory disturbance index (RDI) by PRRD was observed. Accuracy of the PRRD was evaluated in terms of sensitivity and specificity for different RDI-PRRD cut-off points with respect to AHI-PSG >10 and AHI-PSG >30. A logistic regression model was performed to estimate the chance per unit of RDI of apnoeas. A received operating characteristic (ROC) curve was drawn to obtain the sensitivity/specificity profile for each observed RDI value obtained. From the ROC curve the authors identified the better cut-off points, which represent a balanced sensitivity/specificity. Through a classification table defined by the cut-off point, the post-odds to exhibit the disease was calculated. For a full PSG cut-off point of 10 a PRRD of six showed a balanced sensitivity of 95% and a specificity of 92%. For a full PSG cut-off point of 30 a PRRD of 16 shows a balanced sensitivity/specificity (100% and 97%, respectively). Post odds of apnoea were calculated for each cut-off point.

In conclusion, these data suggest that the portable respiratory recording device is an effective device to identify apnoeas and hypopnoeas in a general population and is therefore a suitable device to be used in epidemiological studies.

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Published and ongoing studies emphasize the high prevalence of sleep apnoea-hypopnoea syndrome (SAHS) [1–2]. The main consequences of this disorder are probably: increase cardiovascular morbidity and mortality [3–6]; traffic accidents [7, 8] and quality of life impairment [9]. However, this increased risk can be attenuated as an effective treatment exists for symptomatic patients [3, 10, 11]. Conventional polysomnography (PSG) is considered the "gold standard" for the diagnosis of sleep disordered breathing [12, 13]. However, this standard has a high cost and it is only available in specialized centres. The high prevalence of the disease, accessibility, long waiting lists and cost problems are the main reasons that justify research into more available and less expensive but comparably effective diagnostic alternatives.

Previous studies have shown that an accurate diagnosis of sleep disordered breathing can be made without using neurological variables even in a nonattended setting [14–17]. These devices could be very useful not only for the management of subjects with suspected (SAHS) but also

for epidemiological studies. Various portable monitoring systems and protocols have been developed in an attempt to achieve this goal [15–29]. However, most of them have been validated only in subjects with suspected SAHS but not in a large enough number of subjects from the general population.

The aim of the current study was to validate the use of a simplified respiratory polygraph in a sample from a general population of an ongoing epidemiological study. Overall sensitivity and specificity of this portable respiratory recording device (PRRD) for sleep apnoea and hypopnoea was assessed, using full PSG as the gold standard.

### Materials and methods

#### Study subjects

The study population consisted of a sample of 116 subjects recruited from the general population in the context of

an ongoing epidemiological study in the population of Mataró in Barcelona (Spain). The Human ethics committee of the hospital approved the protocol and informed consent was obtained from all patients.

### Study design and methods

The sleep studies were performed in the Sleep Laboratory at the Hospital Clínic of Barcelona (Spain). Subjects were admitted to the sleep laboratory in the evening and were prepared for simultaneous application of conventional PSG (SleepLab 1000P; Jaeger, Wuerzburg, Germany) and the new PRRD (Sibel Home-300; Sibel S.A., Barcelona, Spain). The sensors were unique for each recording system. Once the set-up was completed subjects were allowed to sleep overnight. Signals from the PSG were stored in the computerized polygraph (SleepLab 1000P for Windows; Aequitron Medical Inc., Minneapolis, MN, USA). Signals from PRRD were stored in the Sibel-Home unit. The data from PSG and PRRD recordings were analysed separately (blindly, independently) without knowledge of the results of the other system.

### Conventional polysomnography

This procedure included the recordings of electroencephalogram (EEG; C3/A2, F1/A1, O1/A2), chin electromyogram (EMG) and electro-oculogram recordings for sleep staging according to the established standard criteria [30]. Arterial oxygen saturation ( $S_{a,O_2}$ ) was measured continuously with a finger probe using a pulse oximeter (504 Critical Care System Inc., Waukesha, WI, USA). Ribcage and abdominal motion were monitored using bands placed over the thorax and abdomen. Airflow was assessed using a thermistor. All signals were recorded continuously through a polygraph, SleepLab 1000P (Aequitron Medical Inc.). Respiratory events were scored as apnoea when there was a cessation of airflow lasting  $\geq 10$  s, and hypopnoea when any clear discernible reduction of airflow lasting  $\geq 10$  s was observed, associated with an arousal or with at least 3% dip in  $S_{a,O_2}$ . Arousals were defined according to the scoring rules of the American Sleep Disorders Association [31]. Microarousals were defined as an abrupt shift in the EEG frequency that may include theta, alpha or frequencies  $>16$  Hz between 1.5–3 s of duration always with EMG activation. A PSG apnoea-hypopnoea index (AHI)  $>10$  was considered abnormal. A PSG AHI  $>30$  was considered notable.

### Portable respiratory recordings device

The PRRD records nasal/oral airflow (thermisty), chest wall impedance, oxygen saturation, snoring and body position. The morning after the study, the signals were displayed on the computer screen allowing a visual assessment of the overnight tracings. Respiratory events were scored manually using similar criteria as used for PSG. The definition for apnoea was equivalent to PSG, but hypopnoea was considered when any clear reduction in airflow lasting  $>10$  s was associated with at least a 3% dip of  $S_{a,O_2}$ . The respiratory disturbance index (RDI) was estimated taking into account the time spent in bed.

### Data analysis/statistical methods

Arithmetic mean, standard deviation and percentage of cases observed constituted the descriptive analysis. Agreement between RDI obtained from PRRD and full PSG was analysed according to the method of BLAND and ALTMAN [32, 33]. Logistic regression was used to predict the chance of AHI  $\geq 10$  events·h<sup>-1</sup> (or AHI  $\geq 30$  events·h<sup>-1</sup>) using RDI as an independent factor. For these models, RDI determinations were analysed as continuous variables. A receiver operating characteristic (ROC) curve was drawn to show the sensitivity and specificity of each observed value of RDI. The post odds of having the disease was calculated managing the classification table defined by the cut-off point. Ninety-five per cent confidence intervals (95% CI) were calculated for each of the estimates. Significance level was 5%. Software for analysis was STATA (Stata Statistical Software: Release 5.0; Stata Corporation College Station, TX; USA).

## Results

The characteristics of the subjects and main data from the sleep study are summarized in table 1. By conventional PSG, 28 out of 116 subjects (24%) had  $>10$  events·h<sup>-1</sup> and 11 of them (10%) had  $>30$  events·h<sup>-1</sup>. The mean $\pm$ SD AHI obtained by full PSG and PRRD were 9.5 $\pm$ 16 and 6.9 $\pm$ 12. The mean $\pm$ SD total number of apnoeas/hypopnoeas obtained by PSG and PRRD were 46 $\pm$ 81 and 45 $\pm$ 80, respectively ( $p=0.8$ ). The agreement in AHI between full PSG and PRRD using the method suggested by BLAND and ALTMAN [33] showed the following results: the difference average (RDI-AHI) was -2.7 (95% limits of agreement, BLAND and ALTMAN [33] (-15.5–10.1) (fig. 1). Only two cases were outside the limits of agreement.

As mentioned, the diagnostic accuracy of the PRRD was evaluated in terms of sensitivity and specificity, obtained through a ROC curve by taking different AHI-PRRD cut-off points with respect to an arbitrarily diagnostic AHI-full PSG  $>10$  and a presumptive notable number of respiratory events of AHI-full PSG  $>30$ .

Table 1. – Summary characteristics of the general population

Subjects	116
Sex M/F	65/51
Age yrs	47 $\pm$ 12
BMI kg·m <sup>-2</sup>	26 $\pm$ 4
Sleep efficiency %	76 $\pm$ 13
Stage I %	11 $\pm$ 10
Stage II %	51 $\pm$ 9
Delta sleep %	21 $\pm$ 10
REM sleep %	16 $\pm$ 7
No. arousals/microarousals	25 $\pm$ 27
AHI PSG events·h <sup>-1</sup>	9.5 $\pm$ 12
RDI PRRD events·h <sup>-1</sup>	6.9 $\pm$ 12
Total No. A/H PSG	46 $\pm$ 81
Total No. A/H PRRD	45 $\pm$ 80

Data are mean $\pm$ SD. M: male; F: female; BMI: body mass index; REM: rapid eye movement; AHI: apnoea/hypopnoea index; PSG: polysomnography; RDI: respiratory disturbance index; PRRD: portable respiratory recording device; A: apnoeas; H: hypopnoeas.

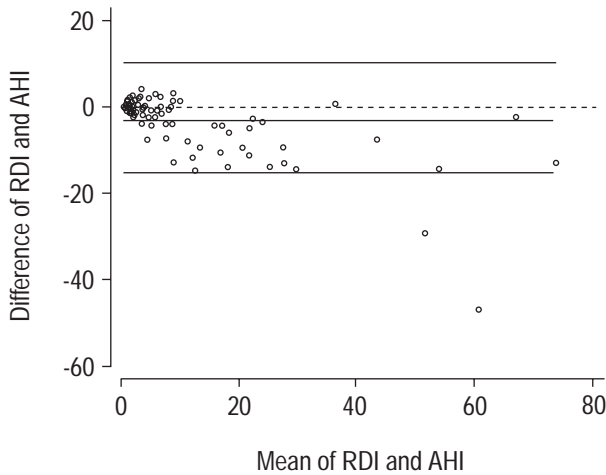


Fig. 1. – Comparison of apnoea/hypopnoea index (AHI) by the two methods (respiratory disturbance index (RDI)- portable respiratory recording (PRRD)) and (AHI)- full polysomnography. The solid line, below the dashed line corresponding to zero, represents the mean bias of the individual differences, and both lines at the extremes represent the limit of agreement. The analysis of the degree of concordance (BLAND and ALTMAN method [33]) indicate that the consistency of the two measures can be expected if its difference is found to be approximately in the range -16–11.

*Polysomnography cut-off point >10*

According to the PSG diagnostic lower limit, a gold standard cut-off point of AHI >10 events·h<sup>-1</sup> was selected and adjusted through a logistic regression model obtaining the following results: each time that RDI is increased by one unit, the odds for apnoea/hypopnoea are increased by times 1.63 (=e<sup>0.49</sup>); 95% CI 1.31–2.01. Thus, the estimated model was the following:

$$\log(1/p - p) = -4.29 + 0.49 \text{ RDI},$$

where p is the estimated probability for apnoea/hypopnoea. A ROC curve was drawn to show the sensitivity/specificity of each observed value of RDI (fig. 2). For a full PSG cut-off point of 10, a PRRD of 2 events·h<sup>-1</sup> shows a sensitivity of 100% and a specificity of 68%, a PRRD of 10.3 events·h<sup>-1</sup> shows a sensitivity of 75% and a specificity of

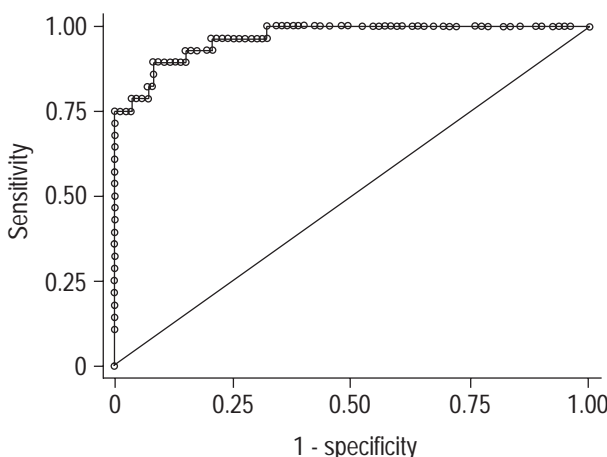


Fig. 2. – Receiver operating characteristics (ROC) curve showing the sensitivity/specificity of each observed value of respiratory disturbance index (RDI) obtained by night-time portable respiratory recording device (PRRD) (RDI-PRRD) in relation to full polysomnography cut-off point of 10. The area under the ROC curve = 0.9667.

100% and a PRRD of six shows a balanced sensitivity of 89% (95% CI: 72–98%) and specificity of 92% (95% CI 84–97%). Figure 3a shows the classification table for a cut-off of 10. The odds pretest for apnoea is 28/88 (~1/3) which means that, in this sample, one from each four are positive. The odds post to have apnoea/hypopnoea is therefore 25/7 (~7/2), which implies that approximately seven out of nine are true positives if they were positive in the test (RDI >6 events·h<sup>-1</sup>) (25 of 32 are true positives if they were positive in the test).

*Polysomnography cut-off point >30*

For a gold standard cut-off point of an AHI >30 events·h<sup>-1</sup> and adjusting a logistic regression model the authors obtained the following results. Each time that RDI is increased by one unit, the odds for apnoea/hypopnoea are increased by times 1.75 (=e<sup>0.56</sup>); 95% CI 1.01–3.07. Thus, the estimated model is the following:

$$\log(p/1 - p) = 11.55 + 0.56 \text{ RDI}$$

where p is the estimated probability for apnoea/hypopnoea. A ROC curve was drawn to show the sensitivity/specificity of each observed value of RDI (fig. 4). For a full PSG cut-off point of 30, a PRRD of 16 events·h<sup>-1</sup> shows a sensitivity of 100% (unilateral CI: 97.5: (71.5–100%) and a specificity of 97% (95% CI: 91.9–99.4). The pretest odds for apnoea is 11/105 = 1/10 which means that in this sample, one from each 11 are positive. The odds post to have apnoea/hypopnoea is thus 11/3, which implies that 11 out of 14 are true positives if they have been positive on the test.

**Discussion**

This study shows that the use of a PRRD is an adequate tool to detect sleep apnoea and hypopnoea during sleep in a general population. The close agreement obtained between AHI by PRRD and PSG makes the former a qualified method for detecting the presence of apnoea and hypopnoea.

a)

		Gold standard		Total
		+	-	
RDI	+	25	7	32
	-	3	81	84
Total		28	88	116

b)

		Gold standard		Total
		+	-	
RDI	+	11	3	14
	-	0	102	102
Total		11	105	116

Fig. 3. – Classification for a cut-off of 10 events·h<sup>-1</sup> (a) and of 30 events·h<sup>-1</sup> (b). RDI: respiratory disturbance index. +: positive; -: negative, diagnosis according to cut-off points. For RDI (a), +: >6 events·h<sup>-1</sup>; for RDI (b), +: >16 events·h<sup>-1</sup>.

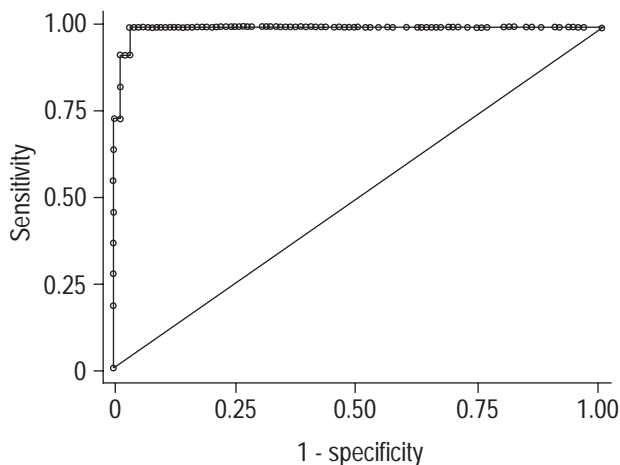


Fig. 4. – Receiver operating characteristics (ROC) curve showing the sensitivity/specificity of each observed value of respiratory disturbance index (RDI) obtained by nighttime portable respiratory recording device (PRRD) (RDI-PRRD) in relation to full polysomnography cut-off point of 30. The area under the ROC curve = 0.9957.

Its valuable sensitivity and specificity at the two PSG cut-off points selected (10 and 30 events·h<sup>-1</sup> of sleep) validate the diagnostic accuracy of the PRRD method. Therefore, the authors think that PRRD is a useful tool to be used in epidemiological studies.

As with any diagnostic test proposed it is important to define the target population to which the test is applied. There are usually considerable methodological problems when applying data from one study to a different type of patient. The current study was conducted to obtain relevant data on the feasibility of the PRRD for screening purposes in nonselected subjects from a general population. Thus, an *a priori* selected PSG cut-off point of <10 and <30 was chosen for the purpose of diagnostic screening and for grading the severity, respectively.

In spite of the fact that full PSG continues to be the reference diagnostic method to detect obstructive sleep apnoea (OSA) [12, 13], growing clinical awareness of the frequency and consequences associated with sleep apnoea and hypopnoea syndrome have led to a search for systems that allow a reliable diagnosis at a lower cost in a friendly environment. In the authors' opinion, this type of system needs to have two characteristics: they have to be simple (low number of variables) and must allow home studies. In relation to the first point, several studies have demonstrated this PRRD'S utility but most of them have been performed in patients with suspected SAHS and not in general population. To the authors' knowledge, this is the first evaluation study with a simplified polygraph set-up with a large enough number of patients enrolled from a general population. In patients with suspected SAHS it has been demonstrated in previous studies [15–29] that PRRD is an adequate procedure to detect sleep apnoea and hypopnoea.

Regarding the general population, and with the cut-off point obtained for a PSG of 10, the high sensitivity with only few false negative results allows the use of the PRRD for epidemiological screening. PRRD devices have, however, certain drawbacks that should be mentioned. Other sleep disorders than SAHS can be missed. Owing to the absence of measurement of neurological variables it is not

possible to determine the sleep time and thus the calculated scores of the PRRD refer to the recording time, which only barely corresponds to the sleep time. In the current study, both systems, PSG and PRRD detected a similar number of events and, consequently, the main reason for the discrepancy in AHI was the sleep efficiency.

The other concern is the possibility of performing home studies. Aside from the previously mentioned fact of an ongoing epidemiological PRRD home study, for validation purposes the authors studied the general population simultaneously with full PSG at the sleep laboratory. In a previous work in patients suspected of having SAHS, it has been demonstrated that the use of a PRRD at the patient's home is a reliable method for diagnosis with a more than acceptable cost-effective profile [15]. Specifically, the diagnosis of OSA by PRRD, including repeated studies and those in which finally full PSG was necessary, was about three times more efficient than using only conventional PSG. Furthermore, in relation with the setting of the study, two factors need to be taken into account. Firstly, in the sleep laboratory an attending technician was present for all of the study night and secondly, sleeping outside patient's home with all sensors connected could account for the decrease in sleep efficiency or modify the sleep architecture. Alternatively, when PRRD is used at home the quality of the signals obtained without the presence of an attending technician may reduce the signal quality control. Therefore, despite the fact that these results validate the utility of the PRRD with respect to full PSG, extrapolation of the results to a nonattended home setting remains to be elucidated. In this study, the authors have focused, not on the environment in which the patients are, but, instead, on the equipment performance in the detection, reproducibility and accuracy aspects which always have to be compared to the gold standard. The authors are aware that the AHI can be underestimated using a simplified apparatus without taking into account sleep efficiency. However, the underestimation of AHI with a simplified apparatus may well be balanced by other factors not considered in the conventional PSG setting. Thus, factors such as the mattress, the pillow, natural sleeping position, sharing the bed, sound conditions or cableless, etc, are different between homes and, also quite different from what occurs in the sleep laboratory. This situation may overweight the decrease in AHI when the bed time is taken into consideration instead of the sleep time for others and the current authors' experience [15, 20], 8–10% of the studies must be repeated when PRRD is applied at home.

Although the cut-off point has been specifically selected that best fits with the finest sensitivity/specificity profile, attending to other specific issues to be accomplished, the method permits the obtainment of other cut-off points that improve either sensitivity or specificity.

Finally, a possible criticism of the study is the utilization of a thermistor instead of the nasal cannula. The authors are aware, as other groups are, that nasal cannula is a more sensitive method for the detection of obstructive respiratory events. However, as yet the utilization of nasal cannula is far from standardized since not even any reference values are currently available. In addition, the authors feel that the correct use and interpretation of nasal cannula signal require a period in which both devices are to be used simultaneously. Owing to these considerations and, for the

purpose of a prevalence study in which outcome variables are to be compared to other studies, it was decided to use the thermistor. In addition, it is the authors' belief that if they are concerned with the thermistor limitations in respiratory events detection, the problem becomes relatively less crucial when taking in account its inconveniences. In any case, thermistor always underestimates the AHI.

In conclusion, these data suggest that the portable respiratory recording device is an effective and reproducible device to identify apnoea and hypopnoea in a general population. General implementation of these devices could strikingly reduce the number of full-polysomnography studies needed, and can also be used with confidence for epidemiological studies.

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