



Validation of a Portable Respiratory Monitoring System for the Diagnosis of Obstructive Sleep Apnea in Patients with Chronic Obstructive Pulmonary Disease: A Crossover Study

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Abstract

Introduction Portable respiratory monitoring (PM) has been used to diagnose obstructive sleep apnea (OSA) in the general population. However, its validation in patients with both OSA and chronic obstructive pulmonary disease (COPD), remains unclear.

Objective The aim of the study was to validate PM for the diagnosis of OSA in patients with COPD.

Materials and Methods In this cross-sectional study, COPD patients were submitted simultaneously to polysomnography (PSG) and PM. Moreover, the risk for OSA was verified by the Berlin, NoSAS, and STOP-BANG questionnaires. Sensitivity, specificity, positive predictive value, and negative predictive value for PM were calculated for the cutoff points of the hypopnea apnea index (AHI) of 5, 15, and 30 events/hour, as well as for the questionnaires. The Bland-Altman test and correlation analyses between the AHI of the PSG and PM were performed.

Results A total of 103 patients were evaluated (age 67.5 ± 9.9 years, 60% men). The STOP-BANG questionnaire had the highest sensitivity for OSA diagnosis, at 94.4% (72.7–99.9%). The sensitivity of PM decreased (87.0, 66.7, and 44.4%), and the specificity increased 40.0, 78.6, and 100.0%) as the AHI cutoff point increased from 5, 15, and 30. The Bland-Altman test indicated good limits of agreement ($AHI = 5.5 \pm 11.7$ events/hour). Therefore, the AHI results of the PM showed a strong and positive correlation with those of the PSG ($r = 0.70$, $p < 0.0001$).

Conclusion The PM test can be a useful tool for OSA diagnosis in patients with COPD.

Keywords

- obstructive sleep apnea
- validation studies
- sleep breathing disorders

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Introduction

Obstructive sleep apnea (OSA) affects 23 to 49% of the general population^{1,2} and can coexist with other respiratory diseases, such as chronic obstructive pulmonary disease (COPD).³ Up to 66% of COPD patients can have OSA, characterizing an overlap syndrome.⁴ In this disease, in addition to chronic airway obstruction, the desaturation that occurs during sleep and leads to a higher risk of pulmonary hypertension may not reflect sleep apnea, but COPD itself.^{5,6}

The overnight polysomnography (PSG) is the gold standard for the diagnosis of OSA since it allows precise measurement of sleep and relevant cardiorespiratory and neurologic behaviors.⁷ However, due to the scarce availability and high expenses of both highly trained personnel and associated technology, it may not be widely used in health assistance.⁸ In this sense, although previous studies have validated portable respiratory monitoring (PM) in comparison with PSG in the general population,⁹ as well as in some populations with comorbidities such as heart failure,¹⁰ obesity,¹¹ and COPD,¹² and its ease of use at home, the efficacy of PM for the diagnosis of the overlap syndrome remains unclear.

Thus, the aim of this study was to validate PM for the diagnosis of OSA in patients with COPD when compared to PSG, as well as to verify the performance of sleep questionnaires in this population.

Materials and Methods

Study Design and Subjects

A cross-sectional study was conducted with patients of both genders, aged between 30 and 85 years, with a confirmed diagnosis of COPD in the pulmonary function test, forced expiratory volume in 1 second (FEV1)/forced vital capacity (FVC) ratio < 0.70, and FEV1 < 80% of predicted, without hospitalization in the last 3 months, recruited from 3 tertiary centers. After initial evaluation, patients performed the sleep study in a single night, with PSG and PM, simultaneously. The local Ethics Committee of the Hospital Universitário Oswaldo Cruz and the Pronto Socorro Cardiológico de Pernambuco (PROCAPE), both from the University of Pernambuco (UPE), approved the protocol, under the number 3.127.151 (January 31, 2019). All patients signed an informed consent form.

Patients with other respiratory diseases, those with a previous diagnosis of OSA, obese with a body mass index (BMI) > 40 kg/m², with neurological diseases, using home oxygen therapy, and those with no availability to attend a sleep laboratory exam were excluded. Moreover, as this research was part of a larger project which analyzed inflammatory markers, the COPD patients who are active smokers were excluded to reduce the interference of smoking on this variable.

Sleep Study

All patients underwent PSG in the sleep laboratory with an Alice 6 standard equipment (Philips Respironics, Philips, Amsterdam, Netherlands), equipped with the following

channels: electroencephalogram, electrooculogram, submental electromyogram, electromyogram of the left and right anterior tibial muscle, electrocardiogram, two thoracoabdominal stress straps with inductance plethysmography, oronasal airflow (thermistor and pressure cannula), pulse oximetry, and body position. The stages of sleep were determined by an experienced observer according to the recommendations of the American Academy of Sleep Medicine (AASM).¹³ Apnea was defined as a reduction in air flow > 90% for more than 10 seconds and hypopnea, as a reduction in air flow > 30% associated with oxygen desaturation > 3%, or the presence of arousal.¹³

The ApneaLink Plus (ResMed, San Diego, CA, United States) was the PM device used simultaneously to assess the following parameters: pulse oximetry, heart rate (from the oximeter probe), air flow (nasal pressure cannula), and respiratory effort (piezoelectric brace placed in the middle of the chest). The score obtained was analyzed by an expert observer blinded to the PSG results. The definitions of apnea and hypopnea were the same for both tests.¹³ Total recording time (TRT) was defined as the time from lights off to lights on. For this, an experienced technician initiated the recording of both PM and PSG simultaneously. The total sleep time (TST) was comprised as the total amount of sleep time from sleep onset to moment prior to awakening. Both TRT and TST were used to calculate the apnea and hypopnea index (AHI).

The Berlin,^{7,14} Snoring, Tiredness, Observed apnea, high blood Pressure, Body mass index, Age, Neck circumference, and Gender (STOP-BANG),¹⁵ and neck circumference, obesity, snoring, age and sex (NoSas)¹⁶ questionnaires were used to assess OSA risk. They are based on high and low clinical risk, with questions regarding snoring, BMI, systemic arterial hypertension, sleepiness, tiredness, fatigue, neck circumference, and age.

Statistical Analysis

The sample size was calculated based on data from PM validation in other population¹¹ with a power of 80% and $\alpha = 0.05$. Demographic variables are described as mean \pm standard deviation (SD) or absolute and relative frequencies. The PSG and PM data were compared using the Wilcoxon test. The Spearman correlation coefficients were calculated for the various dependent measures. Sensitivity, specificity, positive, and negative predictive values in the AHI of 5, 15, and 30 events/hour were calculated from the PSG versus PM. The Bland-Altman plot assessed the mean difference between AHI from PSG and PM. Differences with $p < 0.05$ were considered significant. Statistical analysis and figure construction were performed using the Statistical Package Social Sciences (SPSS, IBM Corp., Armonk, NY, USA) version 23.0, and the GraphPad Prism (GraphPad, Boston, MA, USA) version 6.0, respectively.

Results

A total of 162 participants were recruited and 59 were excluded from the analysis (\rightarrow Fig. 1), resulting in a final sample of 103 participants (age 67.7 ± 9.9 years, 60% men) \rightarrow Table 1.

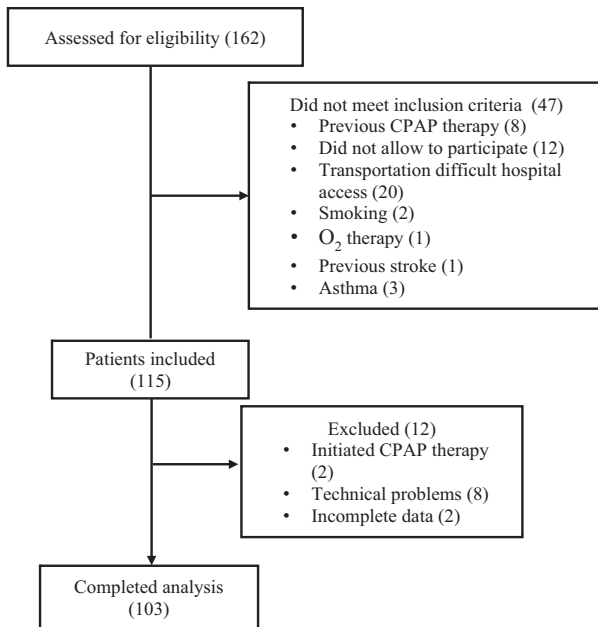


Fig. 1 Study's flowchart.

There were differences in AHI, ODI, basal saturation, average saturation, and percentage of oxygen saturation below 90% (►Table 2) when comparing data between PSG and PM ($p < 0.05$). There was a decrease in sensitivity and an increase in specificity with increasing AHI values (►Table 3). The positive predictive value (PPV) was higher for AHI value ≥ 5 whereas the negative predictive value (NPV) increased as the AHI cut-off increased from ≥ 5 to ≥ 30 and ≥ 30 .

The sensitivity, specificity, PPV, and NPV of Berlin, NoSas and STOP-BANG questionnaires for AHI values ≥ 5 , ≥ 15 , and ≥ 30 are presented on ►Table 4. The highest values for sensitivity were verified in Stop-Bang as the cutoff point of AHI increased whereas the highest values of specificity was verified in the NoSas questionnaire. The PPVs were higher in NoSas and STOP-BANG questionnaires with reductions as the AHI increased, whereas the NPV was higher in the STOP-BANG questionnaire with increases as the AHI increased.

►Figure 2 shows the Bland-Altman analysis with the correlation limits of agreement between PM and PSG. The mean AHI difference between the two diagnostic methods was 7.3 ± 16.4 whereas only 6 out 103 participants were beyond the limits of correlation. Significant correlations were verified between PM and PSG in AHI, ODI, mean oxygen saturation, time of oxygen saturation below 90%, basal saturation, and lowest saturation (►Fig. 3).

Discussion

This study demonstrates that PM may be used for OSA diagnosis among patients with COPD. In addition, the sensitivity and PPV of the PM decreased whereas the specificity as well as the NPV increased with OSA severity. Finally, the STOP-BANG questionnaire demonstrated the best sensibility for OSA diagnosis.

Table 1 Clinical characteristics of the studied population.

Variables	mean \pm SD
Age, years	67.7 \pm 9.9
Male gender, n (%)	62 (60%)
BMI, Kg/m ²	26.3 \pm 5.3
Cervical circumference, cm	37.1 \pm 5.4
Abdominal circumference, cm	97.0 \pm 18.8
Risk (Berlin, high-risk)	70 (68.0%)
STOP-Bang (high-risk)	84 (81.6%)
NoSas (high-risk)	71 (68.9%)
OSA severity	
None	17 (16.5%)
Mild	34 (33%)
Moderate	29 (28.2%)
Severe	23 (22.3%)
FEV1, L	1.2 \pm 0.6
FEV1%	45.5 \pm 17.8
FVC, L	2.2 \pm 0.8
FVC%	76.0 \pm 43.1
FVE1/FVC	0.6 \pm 0.1
COPD classification	
GOLD A	17 (16.3%)
GOLD B	49 (47.1%)
GOLD C	1 (1.0%)
GOLD D	36 (34.6%)

Abbreviations: BMI, body mass index; SD, standard deviation; F, female; FEV1, forced expiratory volume in 1 second; FVC, forced vital capacity; M, male; NoSas, neck circumference, obesity, snoring, age and sex; OSA, obstructive sleep apnea.

The values of sensitivity, specificity, PPV, and NPV observed in the present study agree with those observed in a previous study.^{11,17} These indicate that PM is useful and has a high sensitivity for the diagnosis of OSA, especially for AHI > 5 events/hour. However, the low sensitivity for AHI > 30 events/hour suggests that PSG should be considered in symptomatic patients with normal PM exams. Another interesting finding was the high specificity and NPV values for AHI > 30 events/hour, suggesting that PM with those results can avoid PSG in selected cases.

The AHI from PM and PSG were different. Another unexpected finding was that the hypopnea index was also higher in PM than PSG. When scoring hypopnea without sleep assessment, the number of occurrences tends to be lower due to the impossibility of such scores only being associated with arousal. One possible explanation is the higher desaturation indexes in PM (IDO and saturation $< 90\%$, % of time), which can be explained by different sensitivities of the oximetry sensors. Another possible explanation is that patients with COPD can present desaturation without respiratory events, which can contribute to oximetry oscillations

Table 2 Comparison of respiratory parameters assessed by PSG and PM.

Variables	PSG	PM	p-value
AHI, events/hour	15.6 (6.6–31.4)	13.8 (5.1–20.5)	0.000
Apnea, events/hour	5.6 (2.0–7.6)	3.8 (2.0–7.9)	0.043
Hypopnea, events/hour	10.0 (3.1–12.0)	10 (4.2–20.)	0.001
Lowest saturation O ₂ , %	86.0 (79.5–89.0)	84.0 (79.5–88.0)	0.130
ODI	8.6 (3.3–18.5)	12.0 (5.2–21.0)	0.020
Basal saturation, %	95.0 (93.0–96.0)	96.0 (93.5–97.0)	0.003
Average saturation, %	95.0 (93.0–96.0)	93.0 (90.5–95.0)	0.000
Saturation < 90%, % of time	0.4 (0.0–3.0)	4.0 (1.0–29.5)	0.000
TRT, min	400.0 (366.7–417.0)	385.1 (361.2–403.0)	0.153
TST	287.8 (222.1–310.6)	–	–

Abbreviations: AHI, apnea-hypopnea index; O₂, oxygen; ODI, oxygen desaturation index; PSG, polysomnography; PM, portable monitoring; TRT, total recording time; TST, total sleep time.

Table 3 Sensitivity, specificity, PPV, and NPV for different cut-offs of AHI from the PSG versus AHI from portable PSG.

	Sensitivity	Specificity	PPV	NPV
AHI ≥ 5	84.9 (75.5–91.7)	47.4 (24.5–71.1)	87.9 (82.5–91.9)	40.9 (25.8–58.0)
AHI ≥ 15	68.5 (54.5–80.5)	80.4 (66.9–90.2)	78.7 (67.3–86.9)	70.7 (61.4–78.5)
AHI ≥ 30	44.4 (25.5–64.7)	96.2 (89.2–99.2)	80.0 (55.0–92.9)	83.3 (78.1–87.5)

Abbreviations: AHI, apnea-hypopnea index; NPV, negative predictive values; PSG, polysomnography; PPV, positive predictive values.

Table 4 Sensitivity, specificity, VPP, and VPN for different cuts of the PSG, AHI, and of the Berlin, NoSas, and STOP-BANG questionnaires.

	Sensitivity	Specificity	VPP	VPN
Berlin				
AHI ≥ 5	67.4 (56.5–77.2)	36.8 (16.3–61.6)	82.9 (76.9–87.5)	20.0 (11.4–32.7)
AHI ≥ 15	66.7 (52.5–78.9)	33.3 (20.8–47.9)	51.4 (41.5–61.3)	51.4 (35.5–61.9)
AHI ≥ 30	70.4 (49.8–86.2)	36.6 (24.2–46.2)	27.1 (21.7–33.3)	77.1 (63.6–86.7)
NoSas				
AHI ≥ 5	67.4 (56.5–77.2)	31.6 (12.6–56.6)	81.7 (76.1–86.2)	17.6 (9.4–30.8)
AHI ≥ 15	75.9 (62.4–86.5)	41.2 (27.6–55.8)	57.7 (51.0–64.3)	61.8 (47.6–74.2)
AHI ≥ 30	81.5 (61.9–93.7)	37.2 (26.5–48.9)	31.0 (25.9–36.5)	85.3 (71.4–93.1)
STOP-BANG				
AHI ≥ 5	81.4 (71.6–89.0)	26.3 (9.2–51.2)	83.3 (79.0–87.0)	23.8 (11.6–42.8)
AHI ≥ 15	85.2 (72.9–93.4)	25.5 (14.3–39.6)	54.7 (49.9–59.5)	61.9 (42.4–78.2)
AHI ≥ 30	92.6 (75.7–99.1)	24.4 (15.4–35.4)	29.8 (26.4–33.3)	90.5 (70.3–97.4)

Abbreviations: AHI, apnea-hypopnea index; NoSas, neck circumference, obesity, snoring, age, and sex; PPV, positive predictive value; PSG, polysomnography; VPN, negative predictive value.

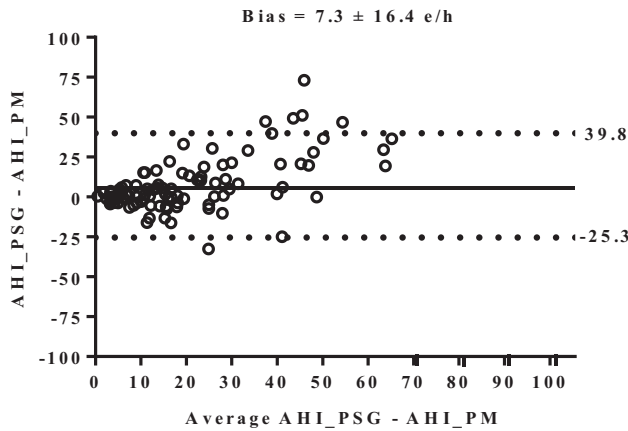


Fig. 2 Bland-Altman graph. Difference in the hypopnea-apnea index (AHI) between polysomnography (PSG) and portable monitoring (PM).

during sleep. Nevertheless, although these differences were statistically significant, they are not clinically relevant.

Finally, it may be speculated that patients with overlap syndrome experience hypoxemia and hypercapnia, which may impair the assessment and classification of respiratory events. Nevertheless, the Bland-Altman test showed a strong agreement between the AHIs from the PSG and PM. Some studies show that the best results occur when the records are made simultaneously in laboratory settings.^{9,18,19} Indeed, Santos-Silva et al.⁹ observed similar AHI values on both the portable monitor and the complete polysomnography performed in the laboratory and, differently from the present study, Oliveira et al.¹⁹ observed similar agreement results.

Finally, the correlation analysis showed that respiratory variables (AHI, oxygen desaturation index, mean, basal, and lowest saturation, and saturation <90%) presented moderate to strong correlation, corroborating with previous study.⁹ It is important to note that approximately 7% of exams were missed with PM due to oximetry and nasal cannula artifacts, but this is reported as a limitation of this tool in general and does not seem to be specific to the population studied.

Our study also showed fewer exclusions due to failure in the sleep study compared to that of Oliveira et al., who carried out two studies with PM in the same patient. Using PM in the laboratory, there was a loss of 22% in Oliveira et al.'s study, while ours showed a loss of 7%. In another study, our team also presented low loss rates in patients with hypertrophic cardiomyopathy (3.25%).²⁰ The different sensitivities of the oximetry sensors may be responsible for these variations, as well as baseline oxygen saturation in patients with pulmonary diseases. Another point to be addressed were the low nocturnal desaturation indexes in a COPD population. However, almost 2/3 of our patients were classified as GOLD A/B stages, and we excluded patients with nocturnal oxygen use.

When analyzing the sensitivity, specificity, PPV, and NPV of the Berlin, NoSas, and STOP-BANG questionnaires, it was observed that the last one presented the highest sensitivity regardless the AHI cutoff and, as expected, all questionnaires presented low specificity. These results corroborate with previous study analyzing the STOP-BANG as tool for screening of OSA patients.¹⁵ Therefore, in clinical settings, this questionnaire could be used as an effective screening tool for OSA regardless of severity.

The strengths of our study are its methodological rigor, the high number of participants, and the simultaneous use of

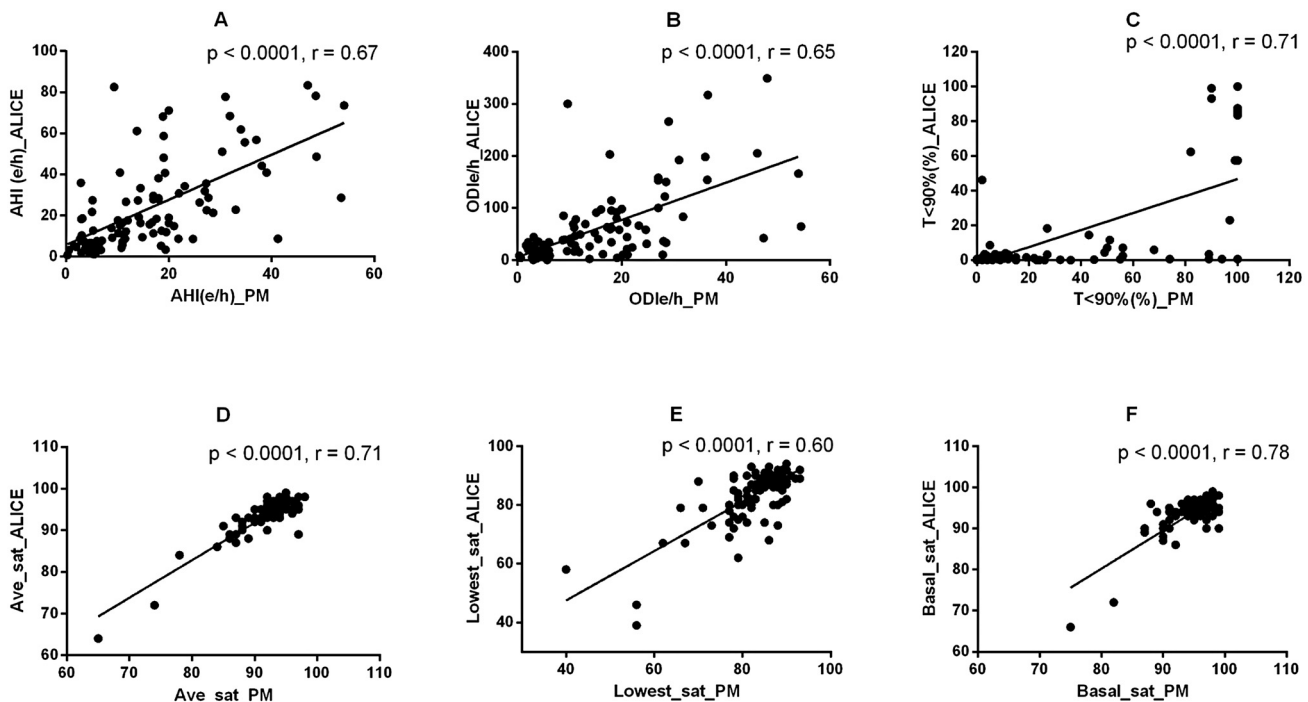


Fig. 3 Correlations between respiratory data from PSG and PM. (A) Apnea-hypopnea index; (B) oxygen desaturation index; (C) saturation lower than 90%; (D) average saturation; (E) lowest saturation; (F) base saturation.

the PM and PSG, which is important to exclude the “second-night effect”, reported by others,^{21–23} that can modify the AHI during different nights. One potential limitation may be sleep disturbance generated by the discomfort of using two PSG equipment, but it has been previously done,^{9,11} and as shown in ►Figure 1, we had few study refusals and the limited generalization to other populations such as smoking and obese patients.

Conclusion

In conclusion, this study shows that the PM can be used for OSA diagnosis in patients with COPD. Furthermore, the STOP-BANG questionnaire may be useful to screen OSA.

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Conflict of Interests

The authors have no conflict of interests to declare.

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