

# Validation of a Respiratory Polygraphy System in the Diagnosis of Sleep Apnea Syndrome

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**OBJECTIVE:** To validate a cardiorespiratory polygraphy system (BITMED NGP 140) by comparing it to conventional polysomnography in the diagnosis of sleep apnea-hypopnea syndrome.

**PATIENTS AND METHODS:** Polysomnography and cardiorespiratory polygraphy were performed simultaneously on 103 consecutive patients referred because of suspected sleep apnea-hypopnea syndrome. The Bland and Altman method and intraclass correlation coefficients were used to assess agreement between the 2 methods of measurement. Receiver operating characteristic (ROC) curves were used to calculate the yield of cardiorespiratory polygraphy compared to that of conventional polysomnography.

**RESULTS:** Ninety-two valid studies were obtained for 72 men and 20 women (mean [SD] age: 52.4 [12] years). By the Bland and Altman method, the difference between the respiratory event index obtained with the BITMED NGP140 and the apnea-hypopnea index (AHI) obtained by conventional polysomnography was 7.6 (13.2) in the manual analysis (95% confidence interval [CI], 4.9-10.4) and 12 (15.3) (95% CI, 8.8-15.3) in the automatic analysis. For a corrected AHI (AH/total time in bed) mean differences were -2.2 (5.9) and 2.4 (8.2) for manual and automatic analyses. The intraclass correlation coefficients were greater than 0.94.

The areas under the ROC curves of the respiratory event index were greater than 0.97 for all cut points. For an AHI of 30 or higher, the best cut-off point determined by manual cardiorespiratory polygraphy analysis was 27 (sensitivity, 98% and specificity, 98%). For the different cut-off points cardiorespiratory polygraphy correctly classified between 92% and 98% of patients in both the manual and automatic analyses.

**CONCLUSIONS:** The BITMED NGP140 had good agreement with conventional polysomnography for the measurement of respiratory events and provided high diagnostic yield.

**Key words:** Sleep apnea. Polysomnography. Polygraphy. Validation study. Sensitivity. Specificity.

Validación de un equipo de poligrafía respiratoria en el diagnóstico del síndrome de apneas durante el sueño

**OBJETIVO:** Validar un dispositivo de poligrafía (PGR) cardiorrespiratoria, BITMED NGP140, frente a la polisomnografía convencional (PSG) en el síndrome de apneas e hipopneas durante el sueño.

**PACIENTES Y MÉTODOS:** Se realizó PSG y, simultáneamente, PGR a 103 pacientes consecutivos enviados por sospecha de síndrome de apneas e hipopneas durante el sueño. Se aplicaron el método de Bland y Altman, y el coeficiente de correlación intraclass para analizar la concordancia de los 2 dispositivos. La rentabilidad diagnóstica de la PGR frente a la PSG se calculó mediante las curvas de eficacia diagnóstica.

**RESULTADOS:** Se obtuvieron 92 estudios válidos, en 72 varones y 20 mujeres con una media de edad ( $\pm$  desviación estándar) de 52,4  $\pm$  12 años. Con el método de Bland y Altman la diferencia del índice de eventos respiratorios del BITMED NGP140 con el índice de apneas-hipopneas (IAH) de la PSG era, en el análisis manual, de 7,6  $\pm$  13,2 (intervalo de confianza del 95%, 4,9-10,4), y en el análisis automático, de 12  $\pm$  15,3 (intervalo de confianza del 95%, 8,8-15,3), mientras que para el IAH corregido (IAH/tiempo total de registro) la media de la diferencia fue de -2,2  $\pm$  5,9 en el análisis manual y de 2,4  $\pm$  8,2 en el automático. Las correlaciones intraclass eran superiores a 0,94.

Las áreas bajo la curva de eficacia diagnóstica del índice de eventos respiratorios eran superiores a 0,97 en todos los puntos de corte. Para un IAH de 30 o superior, el mejor punto de corte del análisis manual de la PGR era de 27 (sensibilidad del 98% y especificidad del 98%). Para los diferentes puntos de corte, la PGR clasificaba correctamente entre el 92 y el 98% de los pacientes tanto con el análisis manual como con el automático.

**CONCLUSIONES:** El BITMED NGP140 tiene una buena concordancia con la PSG en la medición de los eventos respiratorios y ofrece un alto rendimiento diagnóstico.

**Palabras clave:** Apneas durante el sueño. Polisomnografía. Poligrafía. Estudio de validación. Sensibilidad. Especificidad.

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## Introduction

The growing importance of sleep apnea-hypopnea syndrome (SAHS) is due to its high prevalence,<sup>1-3</sup> its social and health repercussions,<sup>4,5</sup> and its clear link to cardiovascular disease.<sup>6-9</sup> For all these reasons, the diagnosis of SAHS is a health issue of considerable

importance. History and physical examination are not enough to diagnose sleep-related breathing disorders with precision,<sup>10,11</sup> or to quantify the severity of such disorders. The American Sleep Disorders Association (ASDA)<sup>12</sup> has classified the necessary complementary tests into 4 levels according to complexity: level I, standard polysomnography (PSG); level II, comprehensive portable PSG; level III, cardiorespiratory polygraphy; and level IV, continuous (single- or dual-) bioparameter recording (eg pulse oximetry).<sup>12</sup>

Conventional PSG is still the gold standard for diagnosing SAHS,<sup>13,14</sup> but it has several disadvantages: high cost, the need for continuous attention, and a considerable investment of time on the part of medical staff.<sup>14,15</sup> Moreover, it has been claimed that the neurophysiological parameters of PSG are not absolutely necessary for the diagnosis and treatment of SAHS.<sup>16</sup> These considerations, together with the scarcity of diagnostic resources, make it necessary to look for alternative methods, such as cardiorespiratory polygraphy, which does not require constant attention and is much less costly than PSG.<sup>12,17,18</sup>

Validation studies have been carried out for some of the respiratory polygraphy systems on the market, and various groups consider them an acceptable alternative to conventional PSG.<sup>12,18-28</sup> In a recent meta-analysis of studies involving 1631 patients, 25 systems were analyzed. These studies showed variability in diagnostic yield, with sensitivity ranging from 78% to 100% and specificity from 62% to 99.5%. This variability, together with the proliferation of respiratory polygraphy devices about which little is known, make it necessary to validate such devices in the sleep laboratory.

The objective of the present study was to validate the diagnostic yield of a respiratory polygraphy system (BITMED NGP 140, Meditel Ingeniería Médica, Saragossa, Spain) comparing it to conventional PSG. The study was designed with 2 complementary aims: the first, to determine the agreement between the apnea-hypopnea index (AHI) and the respiratory event index (REI) obtained with both the manual and automatic analyses of cardiorespiratory polygraphy, and the second, to compare the diagnostic yield of cardiorespiratory polygraphy with BITMED NGP 140 with that of conventional PSG, the gold standard diagnostic method.

## Patients and Methods

### Patients

Between June 2002 and January 2003, 103 consecutive patients referred to our department because of suspected sleep-related breathing disturbances were enrolled. They were informed of the purpose of the study and the absence of complications or adverse effects, and their consent to participate in the study was requested. Patients were referred by outpatient pneumology clinics at public health care centers, and those with respiratory or cardiovascular disease were not excluded.

Following the protocol previously established in our department for the study of patients referred for suspected sleep-related breathing disorders, we collected anthropometric and clinical data prospectively from all patients. Weight in kilograms, height in meters, body mass index ( $\text{kg}/\text{m}^2$ ), neck circumference in centimeters, and arterial blood pressure in mm Hg were recorded. We asked about the presence of excessive daytime sleepiness, habitual snoring, observed apnea, history of pulmonary disease (including type), history of arterial hypertension, and other clinical variables. Daytime sleepiness was scored on the Epworth sleepiness scale (from 0 to 24 points).<sup>30</sup>

### Equipment and Measurements

PSG, used as the gold standard, was performed using a Somnostar  $\alpha$  system (SensorMedics Co, Yorba Linda, California, USA) that recorded the following: electroencephalogram (4 channels: C3-A2, O1-A2, C2-A1, and O21), electro-oculogram, submental and tibial electromyogram, electrocardiogram, thoracic, and abdominal movement (to determine respiratory effort) using piezoelectric belts, airflow using a thermistor airflow sensor with type E thermocouple technology, (sensitivity, 2-30  $\mu\text{V}/\text{mm}$ ), changes in arterial oxygen saturation using a SensorMedics pulse oximeter (SensorMedics Co, Yorba Linda, California, USA) (standard error of oxygen saturation in arterial blood of  $\pm 2\%$ ; of pulse, 1 beat/min, with sampling every 6 seconds), snoring using a piezo crystal sensor, and body position using a gold-plated ball bearing rotary sensor.

Cardiorespiratory polygraphy was performed with a BITMED NGP140 polygraphy system, using XGPLab software (Meditel Ingeniería Médica, Saragossa, Spain). BITMED NGP140 is a level III cardiorespiratory polygraphy system that allows continuous recording and has 10 channels and 2 functioning modes: outpatient (unattended) mode and inpatient (attended) mode. In the outpatient mode, the signals are stored in the internal memory that allows 27 hours of recording. It measures 188 $\times$ 99 $\times$ 35 mm and weighs 600 g. It can either be connected to a power source or run on 4 standard 1.5 V batteries. The XGPLab software automatically analyzes respiratory events using programmable criteria.

The cardiorespiratory polygraphy channels used in the present study were as follows: 2 channels for pulse oximetry (1 for oxygen saturation and the other for pulse), 2 channels for respiratory effort using piezoelectric belts, 1 channel for body position using a gold-plated ball bearing rotary sensor, 1 channel for snoring using a piezo crystal sensor, 1 channel for airflow using a thermistor airflow sensor with type E thermocouple technology, and 1 channel for leg movements using a piezo crystal sensor. The sensors for the cardiorespiratory variables, with the exception of oxygen saturation, heart rate, and leg movements, were similar for cardiorespiratory polygraphy and PSG. Pulse rate and oxygen saturation with the BITMED NGP140 polygraphy system were obtained with a pulse oximeter (Nonin Medical Inc, Plymouth, Minnesota, USA) (standard error of oxygen saturation in arterial blood of  $\pm 2\%$ ; of pulse, 2 beats/min, with sampling every 5 seconds).

The thermistor airflow sensors of both systems detected both oral and nasal signals, and were placed one on top of the other on the patient's upper lip.

Conventional attended PSG and cardiorespiratory polygraphy without simultaneous (online) visualization of the

polygraphy recording were performed simultaneously. The systems were set up by an experienced technician, and both studies began and ended at the same time.

The following criteria were used for both the PSG and cardiorespiratory polygraphy studies: apnea (cessation of oronasal airflow lasting 10 seconds or more) and hypopnea (decrease in airflow of 50% or more for at least 10 seconds, associated with arousals [for PSG only] and/or a decline in arterial oxygen saturation of at least 3%). In PSG, sleep stages were classified according to the guidelines recommended by Rechtschaffen and Kales.<sup>31</sup> The ASDA<sup>32</sup> definition of arousals was used.

Two experienced pneumologists evaluated either the PSG or the cardiorespiratory polygraphy studies. Both recordings were analyzed separately and blindly, with the observer unaware of the results of the other recording method. First automatic and then manual analyses of each cardiorespiratory polygraphy recording were performed, using the same criteria to classify respiratory events. The AHI was obtained by dividing the number of respiratory events recorded by PSG by total sleep time, and the REI by dividing the number of respiratory events recorded by cardiorespiratory polygraphy by total time in bed. Respiratory events were classified as obstructive (accompanied by thoracic and abdominal effort), central (absence of thoracic and abdominal movements), or mixed (when both components were present).

In order to compare the number of respiratory events recorded by PSG and those recorded by cardiorespiratory polygraphy independent of total sleep time, a new variable, the corrected PSG AHI (number of events/total time in bed) was introduced.

The diagnostic yield of AHI measured by PSG was compared to that of REI measured by cardiorespiratory polygraphy. For the former, we used the most widely used cut-off points: 10 or higher, 15 or higher, 20 or higher, and 30 or higher.

Sleep studies were excluded if there were significant errors in PSG or cardiorespiratory polygraphy recording signals according to expert opinion.

One of the fundamental differences between the index obtained by PSG and that obtained by cardiorespiratory polygraphy lies in sleep time. Therefore, whereas other authors have excluded sleep studies with total sleep time less than some arbitrary value (eg, 180 or 240 min), we decided rather to exclude those in which total sleep time was lower than the fifth percentile of the distribution of our series.

### Statistical Analysis

Statistical analysis was carried out using SPSS statistical software, version 9.0 (SPSS Inc, Chicago, Illinois, USA). Variables were analyzed by the Kolmogorov-Smirnov method to assess normality of distribution and the measures of central tendency were expressed as means (SD) or as medians with interquartile ranges, as appropriate.

Two procedures were used to assess the degree of agreement between PSG and cardiorespiratory polygraphy. One was the Bland and Altman<sup>33</sup> method, in which the mean of the paired measurements for the 2 devices was plotted against the difference between them. Results were expressed as means (SD) and 95% confidence intervals (CI), and limits of agreement calculated as  $\pm 1.96$  times the SD of the difference. The intraclass correlation coefficients between the manual and automatic analyses of cardiorespiratory

TABLE 1  
Patient Characteristics (n=92)\*

Characteristics	Mean (SD)	Minimum-Maximum
Age, years	52.4 (11.8)	24-77
BMI, kg/m <sup>2</sup>	31.8 (6.6)	21.9-59.2
NC, cm	41.2 (3.6)	33-50
Epworth scale <sup>30</sup>	11.2 (4.8)	2-22
Total PGR time, min	372.6 (35.7)	241-450
Total PSG time, min	367.6 (34)	241-450
Sleep efficiency, %	75.8 (14.8)	42-100

\*BMI indicates body mass index; NC, neck circumference; PGR, polygraphy; PSG, polysomnography.

TABLE 2  
Results of Manual and Automatic Analyses of the BITMED NGP140 Polygraphy System and of Polysomnography\*

Parameters	PSG	PGR BITMED NGP140	
		Manual Analysis	Automatic Analysis
Apneas + hypopneas/h	31.8 (7-72)	30 (7-52)	20 (5-46)
Apneas/h	22.3 (3-53)	12.4 (2-34)	8 (1-27)
Hypopneas/h	4.8 (2-10)	8.7 (4-20)	6 (3-14)
CAHI	23.2 (5-51)		
Mean SaO <sub>2</sub>	91 (90-93)		93 (91-95)
%SaO <sub>2</sub> <90%	9 (2-57)		4 (1-37)

\*Data are expressed as medians (interquartile ranges). CIAH indicates corrected apnea-hypopnea index; SaO<sub>2</sub>, arterial oxygen saturation assessed by pulse oximetry; %SaO<sub>2</sub><90%, percentage of time with arterial oxygen saturation less than 90%; PSG, polysomnography; PGR, polygraphy.

polygraphy and PSG were also calculated. This method quantifies the reliability between the 2 sets of measurements by calculating the proportion of total variance accounted for by the variance between individuals (variance between individuals plus variance of the difference between measurements).<sup>34</sup>

The diagnostic yield of cardiorespiratory polygraphy compared to PSG was evaluated using receiver operating characteristic (ROC) curves,<sup>35</sup> for which the area under the curve together with its 95% CI were calculated in order to assess overall diagnostic yield. The best cut-off point determined by cardiorespiratory polygraphy was selected for each PSG cut-off point (AHI $\geq$ 10,  $\geq$ 15,  $\geq$ 20,  $\geq$ 30). The diagnostic yield of each cut-off point was expressed in terms of Bayesian analysis: sensitivity, specificity, predictive value, and diagnostic accuracy or efficiency. A *P* value less than 0.5 was considered significant.

### Results

Of a total of 103 patients enrolled during the study period, 11 (11%) were excluded. Seven patients were excluded because their total sleep time was less than 148 minutes (fifth percentile of the sleep time distribution obtained by PSG), 3 patients because of technical errors in the storage of data in or transfer of data from the polygraphy system memory, and 1 because of failure in the airflow signal. No other significant errors were detected in the signals of the parameters analyzed. Informed consent was obtained and no patients refused to participate.

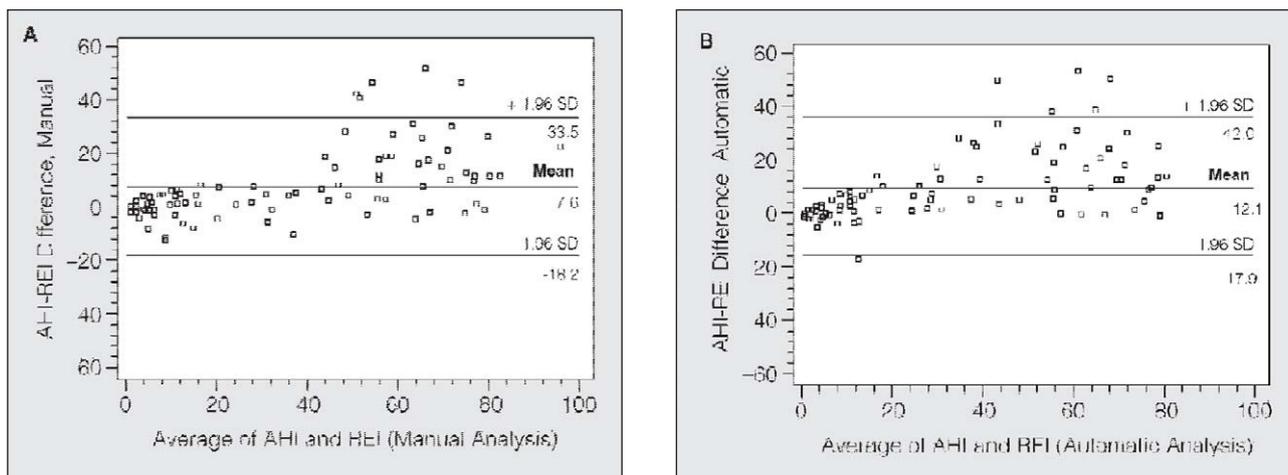


Figure 1. Individual differences between apnea-hypopnea index (AHI) obtained by polysomnography and the respiratory event index (REI) obtained with the BITMED NGP140 polygraphy system, with manual analysis (A) and automatic analysis (B).

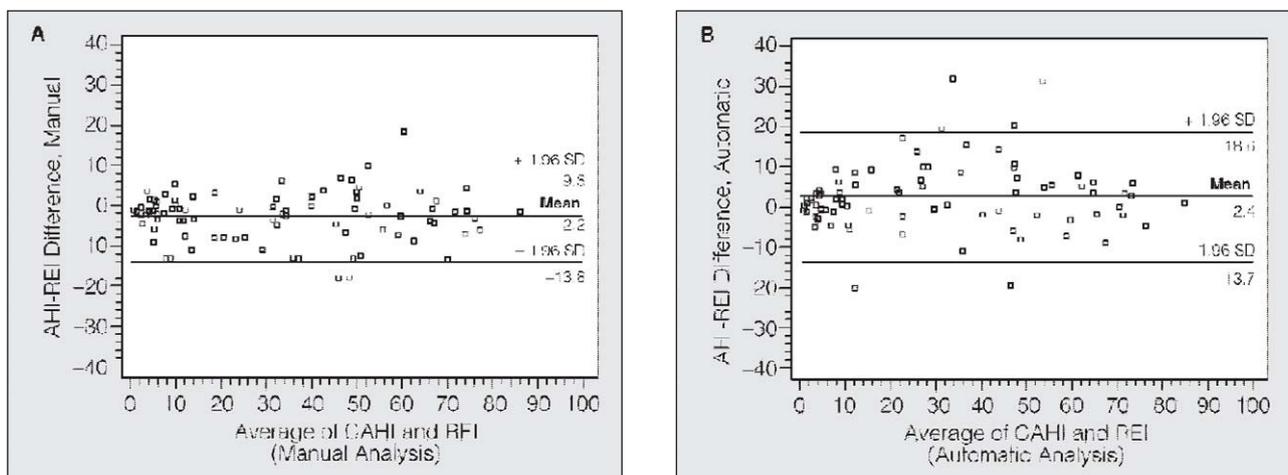


Figure 2. Individual differences between corrected apnea-hypopnea index (CAHI) obtained by polysomnography and the respiratory event index (REI) obtained with the BITMED NGP140 polygraphy system, with manual analysis (A) and automatic analysis (B).

The series consisted of 72 men (78%) and 20 women (22%), with a mean (SD) age of 52.4 (12) years. Other clinical variables are shown in Table 1. Eighty-five percent of the patients had observed apneas, 70% complained of excessive daytime sleepiness, 40% had arterial hypertension, and 8 patients (9%) had chronic obstructive pulmonary disease. Table 1 also shows the mean times of cardiorespiratory polygraphy and PSG recordings, as well as sleep efficiency. Table 2 shows the indices obtained by manual and automatic analyses of both cardiorespiratory polygraphy and PSG. The data were expressed as medians (interquartile ranges) as they did not follow a normal distribution. Given the small number of central apneas observed, we decided not to include this information and to group obstructive and mixed apneas together due to their clinical similarities.

Sixty-five patients (71%) were considered to have SAHS using a PSG AHI cut-off point of 10 or higher. When the criterion was a cut-off point of 15 or higher,

TABLE 3  
Intraclass Correlation Coefficients Between Polysomnography and Manual and Automatic Evaluation of Cardiorespiratory Polygraphy\*

	r (95% CI)
Manual PGR/automatic PGR	0.988 (0.981-0.992)
Manual REI/automatic REI	0.996 (0.995-0.997)
Manual AI/automatic AI	0.950 (0.924-0.967)
Manual HI/automatic HI	0.945 (0.917-0.963)
Manual PGR/PSG	0.907 (0.859-0.938)
REI/AHI	0.777 (0.663-0.853)
Manual PGR AI/PSG AI	0.981 (0.971-0.988)
Manual PGR HI/PSG HI	0.959 (0.938-0.973)
Manual PGR REI/PSG CAHI	0.773 (0.657-0.850)
REI/CAHI	
Manual PGR AI/PSG CAI	
Manual PGR HI/PSG CHI	

\*PSG indicates polysomnography; PGR, polygraphy; AHI, apnea-hypopnea index; AI, apnea index; HI, hypopnea index; REI, respiratory event index; CAHI, corrected apnea-hypopnea index obtained by polysomnography (number of events/hours in bed); CAI, corrected apnea index; CHI, corrected hypopnea index; CI, confidence interval.

TABLE 4  
**Diagnostic Efficiency, by the Area Under the Receiver Operating Characteristics Curve Method, and Best Cut Points According to the Respiratory Events Index Obtained by BITMED NGP140 Polygraphy in Comparison With Various Criteria of the Apnea-Hypopnea Index Obtained by Polysomnography\***

	HAI $\geq$ 10 by PSG	HAI $\geq$ 15 by PSG	HAI $\geq$ 20 by PSG	HAI $\geq$ 30 by PAG
<b>Manual analysis</b>				
Area under the ROC curve, 95% CI	0.971 (0.943-0.999)	0.975 (0.947-1)	0.995 (0.987-1)	0.996 (0.989-1)
REI cut point	7.5	14.8	18.6	26.9
Sensitivity, %	97	96	96	98
Specificity, %	82	94	97	98
PPV	93	96	98	98
NPV	92	94	95	98
Efficiency	92	96	97	98
<b>Automatic analysis</b>				
Area under the ROC curve, 95% CI	0.969 (0.936-1)	0.986 (0.969-1)	0.987 (0.970-1)	0.989 (0.975-1)
REI cut point	5.7	13.5	15.6	15.6
Sensitivity, %	97	92	92	98
Specificity, %	85	97	97	93
PPV	94	98	98	94
NPV	92	90	90	98
Efficiency	93	94	94	95

\*ROC indicates receiver operating characteristics; REI, respiratory event index; AHI, apnea-hypopnea index; PSG, polysomnography; CI, confidence interval; PPV, positive predictive value; NPV, negative predictive value.

56 (61%) were classified as having SAHS. A cut-off point of 20 or higher classified 53 (58%) with SAHS and a cut-off point of 30 or higher gave 48 (52%).

The individual differences between the AHI and the REI obtained with the BITMED NGP140 system and between the corrected PSG AHI (AHI/total time in bed) and the REI were represented graphically using the Bland and Altman method for both manual and automatic analyses. Comparison of PSG and cardiorespiratory polygraphy obtained by manual analysis showed a mean difference of 7.6 (13.2) (95% CI, 4.9 to 10.4; limits of agreement, -18.2 to 33.5), while the mean difference obtained by automatic analysis was 12 (15.3) (95% CI, 8.8 to 15.3; limits of agreement, -17.9 to 42) (Figures 1A and 1B). For the corrected AHI (Figures 2A and 2B), the mean difference between PSG and cardiorespiratory polygraphy obtained by manual analysis was -2.2 (5.9) (95% CI, -3.55 to -1; limits of agreement, -13.8 to 9.3) and 2.4 (8.3) (95% CI, 0.7 to 4.2; limits of agreement, -13.7 to 18.6) for automatic analysis. The intraclass correlation coefficients between the manual and the automatic analyses of cardiorespiratory polygraphy and between PSG and cardiorespiratory polygraphy are shown in Table 3.

In our results, the area under the ROC curve for all the AHI cut-off points (from AHI $\geq$ 10 to AHI $\geq$ 30) provided high diagnostic yield, with values more than 0.97 for both manual and automatic analyses (Table 4). The ROC curves showed better results with cut-off points of 30 or higher in both manual and automatic analyses. Using PSG AHI cut-off points frequently used in the literature, we calculated the best cut-off point for the REI obtained with the BITMED NGP140 polygraphy system, for both manual and automatic analyses (Table 4). For a PSG AHI of 30 or higher, classification with manual analysis of the BITMED

NGP140 system (cut-off point, 26.9) was correct in 98% of patients, with only 1 false negative (REI, 24; sleep efficiency, 73%) and 1 false positive (REI, 34 for an AHI of 28).

The automatic analysis of the BITMED NGP140 recordings, with its corresponding cut-off points, also showed good diagnostic accuracy, with values between 93% and 95%.

## Discussion

In a recent discussion of the present situation of SAHS diagnosis and treatment in Spain,<sup>36</sup> the authors pointed out the insufficient availability of diagnostic resources, with 36% of continuous positive airway pressure treatments prescribed on the basis of nocturnal oximetry (ASDA level IV) alone and 31% of patients diagnosed by respiratory polygraphy (ASDA level III). The number of such level III sleep studies has been increasing, and simpler and smaller devices are being used. However, many of these devices have either not been validated, or have been validated in studies with few patients. The number of patients in the present study was greater than in the majority of published validation studies.<sup>18,19,23,25,27,28</sup>

Another limitation of some of the previous validation studies has been the lack of simultaneity of the 2 methods compared. This introduces innumerable factors of variability, such as differences in sleep time and in the number or type of respiratory events on different nights.<sup>18,37</sup> In the present study, the simultaneity of the 2 recordings eliminated intraindividual variability, a threat to internal validity.

The use of the same sensors for the majority of parameters monitored, a detail not considered in previous validation studies, can help to minimize the

differences between PSG and cardiorespiratory polygraphy recordings. The compatibility of PSG and cardiorespiratory polygraphy sensors is beneficial in a sleep laboratory and offers many advantages not only for the accuracy of the comparison (the objective of the present study), but also in terms of availability and experience in the daily use of the sensors.

A limitation of our study is that it was not population based; rather it included patients selected on the basis of referral to a department specializing in sleep-related breathing disorders. This accounts for certain features of the study, such as the percentage of women (22%) or the mean age of patients, which are characteristic of patients referred for studies of such disturbances.<sup>18,19,22,25,29</sup>

Patients with pre-existing lung or heart disease, in whom the interpretation of cardiorespiratory polygraphy recordings might prove difficult, were not excluded from the study. Such patients have been excluded from some validation studies<sup>27</sup> and some authors believe cardiorespiratory polygraphy to be contraindicated in such cases.<sup>38</sup> We believe, however, that such patients should be included in validation studies, given the high prevalence of these diseases in patients with SAHS.

In previous studies, errors reported in unattended recordings ranged from 2% to more than 10%.<sup>17-19</sup> In our study, the percentage of errors reported in the cardiorespiratory polygraphy recordings was 4%, a percentage we consider acceptable in a complex diagnostic study of long duration.

It may be inferred from the small number of sleep studies we consider invalid because of technical errors that we consider cardiorespiratory polygraphy systems suitable for home use. However, this is not a direct conclusion of our study, as the recordings were carried out in a hospital setting in the presence of health care professionals.

The validation of a cardiorespiratory polygraphy system consists of comparing the device to what is considered to be the gold standard method, PSG. The first step in such a comparison is to determine whether the 2 methods can detect the same events. In our study, the BITMED NGP140 showed very high intraclass correlation and good agreement with PSG with the Bland and Altman method, especially if REI was compared to the corrected AHI, with the same denominator used for both indices. The assessment of agreement between REI and AHI carried out in other studies,<sup>26-28</sup> while useful, is not in our opinion methodologically correct, as the variables compared are not the same. The comparison is more correct when the corrected AHI is used, as it was in our study. Although this correction will not be done when the device is actually in use, it is practical in the context of a validation study, as it helps to assess more precisely how good the correlation is, and whether the limits of agreement obtained with the Bland and Altman method are too wide, and thus of clinical importance.

The agreement between conventional PSG and

cardiorespiratory polygraphy was not as good for hypopneas, for which the correlation coefficient was less than 0.8. We consider this result to be understandable, as the evaluation of hypopnea is more complex than that of apnea, with more criteria involved in its definition (decrease in airflow, oxygen desaturation, arousals, etc).

Another fundamental conclusion of our study was the high diagnostic yield of cardiorespiratory polygraphy with the BITMED NPG140 cardiorespiratory polygraphy system. Unlike other studies,<sup>28</sup> ours showed better diagnostic accuracy with higher REI cut-off points. With the BITMED NGP140 system an REI greater than 26.9 in manual analysis correctly classified 98% of the patients with a PSG AHI of 30 or higher. Diagnostic accuracy was somewhat lower for an AHI cut-off point of 10 or higher, but in this case, a diagnosis of SAHS is more academic than practical and AHIs near 30, considered to be the threshold level for the initiation of continuous positive airway pressure treatment by most specialized associations,<sup>39,40</sup> are probably more useful as a basis for therapeutic decisions.

Another important conclusion of the present study is the high diagnostic yield of the new BITMED NGP140 system with automatic analysis. This automatic analysis, while it does not completely replace the assessment of a qualified technician, does make manual revision of the recordings faster and easier.

In summary, while conventional PSG is still considered the gold standard in the diagnosis of SAHS, cardiorespiratory polygraphy systems offer increasingly accurate diagnoses, proof of which are the results of the present study comparing the BITMED NGP140 polygraphy system with conventional PSG. In our study, which had the advantage of comparing the 2 methods of measurement simultaneously and using mainly the same type of sensors, the BITMED NGP140 showed good agreement in measuring respiratory events and a good diagnostic yield, especially in patients with more than 30 respiratory events per hour. While diagnostic yield was better with manual analysis of the recordings, automatic analysis of respiratory events also offered acceptable diagnostic accuracy and facilitated subsequent manual evaluation.

Level I, II, and III sleep studies should be carried out in all sleep laboratories, with each type being used in the appropriate context. Cardiorespiratory polygraphy is a suitable method for the diagnosis of SAHS, but the cardiorespiratory polygraphy systems used by each laboratory need to be properly validated.

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