Reliability of Home Respiratory Polygraphy for the Diagnosis of Sleep Apnea-Hypopnea Syndrome. Analysis of Costs

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OBJECTIVES: To evaluate the reliability of home respiratory polygraphy for the diagnosis of sleep apnea–hypopnea syndrome (SAHS) and to compare the cost of this technique with that of nighttime polysomnography performed in a sleep laboratory.

PATIENTS AND METHODS: This was a prospective study of a random sample of patients with clinically suspected SAHS in which the participants who underwent both home respiratory polygraphy and nighttime polysomnography were blinded as to the results of their first test. Costs were calculated based on a theoretical population of 1000 individuals. A t test for paired samples, the Pearson correlation coefficient, and a receiver operator characteristic curve were used for the statistical analysis.

RESULTS: The study population was composed of 45 patients with a mean (SD) age of 52.3 (11) years of whom 21 (46.6%) were diagnosed with SAHS, defined by an apnea-hypopnea index greater than 10 in nighttime polysomnography. Comparison of the results obtained in both recordings revealed statistically significant correlations for all comparisons. The optimal cutoff in this population was a respiratory disturbance index of 13.7 or more, for which the area under the receiver operating characteristic curve was 87.5% (95% confidence interval, 74.2%-95.4%). The mean cost of home respiratory polygraphy in a patient with suspected SAHS was €69, whereas that of polysomnography was €179.

CONCLUSIONS: Home respiratory polygraphy is a reliable technique for the diagnosis of SAHS. Using this technique routinely in patients suspected of SAHS will be more economical than using nighttime polysomnography. Uncertain results must be verified by nighttime polysomnography.

Key words: Sleep apnea–hypopnea syndrome. Polysomnography. Home sleep study. Respiratory polygraphy.

Introduction

Sleep apnea-hypopnea syndrome (SAHS) is a prevalent condition in the general population and is associated with marked morbidity and mortality. An apnea-hypopnea index (AHI) greater than 10 per hour of sleep or a...
respiratory disturbance index (RDI) of 5 or above \(^4\) combined with clinical symptoms is considered abnormal. Conventional nighttime polysomnography is the diagnostic test of choice. \(^5\) However, in daily practice, the number of patients diagnosed with SAHS depends on the availability of adequate technology, the number of sleep laboratories, and access to these laboratories \(^6\)–\(^8\); therefore, SAHS is underdiagnosed and its prevalence underestimated.

Alternatives that are less expensive than polysomnography and equally efficacious must be sought to adequately diagnose and treat SAHS. In this sense, respiratory polygraphy has been developed for use outside the sleep laboratory in the patient’s home, thus providing a convenient way to arrive at a diagnosis in a familiar setting. Respiratory polygraphy systems are generally validated in sleep laboratories with the collaboration of laboratory technicians, that is, in a controlled setting. \(^9\)–\(^15\) and very few validation studies have been performed unsupervised in the patient’s home. \(^16\)–\(^19\) Therefore, we propose to validate the use of the Edentec Monitoring System (Edentrace II, Model 3711; Edentec Corporation, Nellcor Puritan Bennett, Eden Prairie, Minnesota, USA) for the diagnosis of SAHS in the home setting in comparison with polysomnography carried out in a sleep laboratory. The main objectives of this study were \(a\) to determine whether home polygraphy can reliably diagnose SAHS (that is, with sufficient sensitivity and specificity), and \(b\) to compare the cost of this method with that of polysomnography performed in the sleep laboratory.

Patients and Methods

This was an independent, blinded validation study. The patients enrolled in the study were selected at random from a population of patients with clinically suspected SAHS who were referred to our respiratory sleep disorders unit in Burgos, Spain. Specific days of the week were assigned in order to select patients using a table of random numbers. The study included patients of both sexes aged between 15 and 75 years who were residents of the Burgos metropolitan area and who reported signs and symptoms of SAHS. Their homes were suitable for a home sleep study and they gave their consent to participate. Patients with the following conditions were excluded from the study: severe concomitant illness (medical or psychiatric), symptoms indicative of sleep disorders other than SAHS, a job in which SAHS would involve an occupational risk, or psychiatric), symptoms indicative of sleep disorders other than SAHS, a job in which SAHS would involve an occupational risk, or symptoms requiring urgent treatment. The study protocol was approved by the clinical research ethics committee of Hospital General Yagüe in Burgos before it started.

For all patients enrolled in the study, a clinical history was recorded oronasal flow by thermistor, chest movements using a chest band, body position by position sensor, snoring by microphone, and heart rate and arterial oxygen saturation by pulse oximetry (SpO\(_2\)). On the night of the study, a trained sleep laboratory nurse went to the patient’s home to set up the polygraph in such a way that the recording could be made unsupervised. The following morning, the patient removed the polygraph and returned it to the sleep unit with the nighttime sleep log. In the sleep unit, the recording was analyzed both automatically and manually.

Apnea was defined as the absence of respiratory flow for at least 10 seconds measured by thermistor. Hypopnea was defined as a decrease of at least 50% in the amplitude of respiratory flow for more than 10 seconds measured by thermistor and a fall in SpO\(_2\) of at least 4%.

Nighttime Polysomnography

Nighttime polysomnography was performed under supervision in the sleep unit or 2 weeks after home polygraphy using the Somntrac 4250 polysomnograph (SensorMedics Corporation, Yorba Linda, California, USA) with 2 electroencephalogram channels (C3/A2; C4/A1), 2 electrooculogram, 2 submental electromyogram, 2 electroencephalogram, and recording of oronasal flow by thermistor, chest and abdominal movements by bands, body position, and SpO\(_2\). For the polysomnography to be considered valid, the patient had to have had at least 180 minutes of effective nighttime sleep. The different sleep stages were evaluated using the conventional criteria of Rechtschaffen and Kales, \(^21\) and arousals were evaluated using the criteria of the American Sleep Disorders Association. \(^22\) The polysomnography recording was analyzed manually and blindly by a person who had not manually the home polygraphy recording and who did not know the results.

Apnea was defined as the absence of airflow through the mouth and/or nose for more than 10 seconds measured by thermistor, and hypopnea as reduced airflow through the mouth and/or nose for more than 10 seconds accompanied by arousals and/or oxyhemoglobin desaturation of at least 4%.

Estimation of Costs

Costs were calculated using the estimations of time and costs per hour of sleep unit staff from the year 2003, as well as the number of tests carried out and the cost of disposable material and maintenance of the polysomnography and respiratory polygraphy equipment. In 2003, an Edentec-type polygraph cost approximately €6010 and its average useful life was estimated to be 5 years. This cost would be increased by the travel expenses of the nurse who visited the patient’s home, the mean distance per night being considered as 8 km; therefore, the estimated cost of home polygraphy would stand at €69.

In 2003, a polysomnography device cost approximately €30 050 and its average useful life was estimated to be 5 years. The estimated cost of polysomnography in 2003 was €179.

The cost of treatment with continuous positive airway pressure (CPAP) was €1.50 per day in 2003, that is, an annual expense of €548 per patient.

Statistical Analysis

The statistical analysis was carried out using SPSS for Windows, version 10.0. Once the data were checked, the absolute and relative frequencies (percentages) were calculated for the quantitative variables, and the mean and SD were calculated for the quantitative variables. Means were compared using the t test for paired samples. The correlation between the RDI in the home polygraphy recording and the AHI in the nighttime
polysonomography recording was determined using the Pearson correlation coefficient.

The receiver operating characteristics curve (ROC) was calculated. For this, different values of the RDI were chosen and an AHI greater than or equal to 10 in the polysomnography recording was considered diagnostic of SAHS. The sensitivity, specificity, positive and negative predictive values, and the positive and negative likelihood ratios of home polygraphy were determined according to the cutoffs chosen in the ROC curve. The positive likelihood ratio was defined as that which expresses how many times more likely it is that a positive result is in patients with the disease than in those without, and the negative likelihood ratio as that which expresses how many times more likely it is that a negative result will be obtained in patients with the disease than in those without. The pretest and posttest diagnostic probabilities of home polygraphy for the diagnosis of SAHS using the pretest odds ratio (prevalence) for the cutoff points determined according to the cutoffs chosen in the ROC curve. Taking an AHI of at least 10 in the polysomnography recording as diagnostic of SAHS, the ROC curve was calculated and different RDI values were identified (figure) (Table 3). The most efficient cutoff point for giving an equal cost of false positives and false negatives (FPC and FNC, respectively) (FPC=1; FNC=1) was an RDI of 11.6. When 2 cutoffs, 1 sensitive and the other specific, were considered for an equal FPC and FNC, the most specific cutoff point was an RDI of 13.7, and the most sensitive cutoff point was 7.2. The most efficient cutoff point for an FPC (FPC=2) double that of the FNC (FNC=1) was an RDI of 13.7, that is, the same point as when FPC is considered as double that of FNC.

**Results**

We studied 45 patients aged between 29 and 75 years. The mean (SD) age was 52.3 (11) years and 39 patients (86.7%) were men. Eight patients (17.7%) had a history of hypertension, 5 (11.1%) heart rhythm abnormalities, 3 (6.6%) heart disease, 2 (4.4%) cerebrovascular accident, 1 (2.2%) chronic obstructive pulmonary disease, and 1 (2.2%) asthma. Of the total number of patients, 44 (97.8%) complained of nighttime snoring, 35 (77.7%) reported nighttime breathing pauses (observed by the sleeping partner), 27 (60%) felt that they had not rested at night, and 20 (44.4%) referred to a feeling of drowning or sudden starts. There were no modifications in alcohol consumption or smoking between home polygraphy and polysomnography.

The baseline situation of the patients before home polygraphy (pre-HP) and polysomnography (pre-PSG) is compared in Table 1. Although statistically significant differences in means were observed between pre-HP and pre-PSG values in daytime sleepiness (Epworth Sleepiness Scale) and neck diameter, these differences were not clinically significant and might be attributable to sample homogeneity. Mean daytime sleepiness score was 8.9 (3) and 8.3 (3) at the pre-HP and pre-PSG assessments, respectively, and the coefficients of variation were similar, 0.40 and 0.45, respectively, which shows the homogeneous nature of both measures.

Of the 45 patients studied, 21 (46.6%; 95% confidence interval, 32%-60%) were diagnosed with SAHS (AHI≥10 in the polysomnography recording). When the values recorded by home polygraphy and polysomnography were compared, the correlations obtained were significant for all the matched pairs (Table 2).

**ROC Curve Values**

Taking an AHI of at least 10 in the polysomnography recording as diagnostic of SAHS, the ROC curve was calculated and different RDI values were identified (figure) (Table 3). The most efficient cutoff point for giving an equal cost of false positives and false negatives (FPC and FNC, respectively) (FPC=1; FNC=1) was an RDI of 11.6. When 2 cutoffs, 1 sensitive and the other specific, were considered for an equal FPC and FNC, the most specific cutoff point was an RDI of 13.7, and the most sensitive cutoff point was 7.2. The most efficient cutoff point for an FPC (FPC=2) double that of the FNC (FNC=1) was an RDI of 13.7, that is, the same point as when FPC is considered as double that of FNC.

**Calculation of Diagnostic Probabilities**

The pretest probability in our population was 0.46, which gave the following posttest probabilities: if we take 2 cutoff points, 1 sensitive and the other specific, and an RDI of 7.2 (sensitive cutoff point) as the

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**TABLE 1**

<table>
<thead>
<tr>
<th>Characteristics of the Patients Studied (n=45)</th>
<th>Pre-HP</th>
<th>Pre-PSG</th>
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<tbody>
<tr>
<td>Neck diameter, cm</td>
<td>40.2 (2)</td>
<td>40 (2)</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>80.4 (9)</td>
<td>79.8 (9)</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>28.7 (4)</td>
<td>28.5 (4)</td>
</tr>
<tr>
<td>Epworth scale</td>
<td>8.9 (3) (0-19)</td>
<td>8.3 (3) (1-22)</td>
</tr>
</tbody>
</table>

Values are expressed as mean (SD).

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**TABLE 2**

<table>
<thead>
<tr>
<th>Results of Home Polygraphy (HP) and of Polysomnography (PSG) in the Study Population (n=45)</th>
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<tbody>
<tr>
<td></td>
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<td>-----------------</td>
</tr>
<tr>
<td>Number of respiratory events</td>
</tr>
<tr>
<td>RDI/AHI</td>
</tr>
<tr>
<td>Duration of events, %</td>
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<tr>
<td>Desaturation index</td>
</tr>
<tr>
<td>Minimum SpO₂, %</td>
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<tr>
<td>Mean SpO₂, %</td>
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<tr>
<td>CT90%</td>
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<tr>
<td>Mean HR</td>
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Abbreviations: AHI, apnea-hypopnea index; CT90%, cumulative percentage of sleep time with SpO₂ less than 90%; HR, heart rate; RDI, respiratory disturbance index; SpO₂, oxygen saturation.

Values are expressed as mean (SD). *P*=0.003. **P**=0.007. †P=0.001. ‡P=0.039. §P=0.001.
diagnostic threshold, the posttest probability of a negative result (RDI<7.2) is 13.6%. If we take an RDI of 13.7 (specific cutoff point) as the treatment threshold, the posttest probability of a positive result (RDI ≥ 13.7) is 92.8%.

In our population, we took the optimal cutoff point to be that obtained after considering FPCs as double the FNCs (FPC=2; FNC=1), that is, an RDI of 13.7 or higher, which gives an area under the curve of 87.5%, with a 95% confidence interval of 74% to 95%, a posttest probability of a positive result of 92.8%, and a posttest probability of a negative result of 25.9%.

Logistic Regression Analysis

A logistic regression model was constructed to predict the presence of SAHS using the RDI values (no SAHS, RDI<13.7; SAHS, RDI ≥ 13.7) and the following covariables: a) presence of daytime sleepiness, if the Epworth Sleepiness Scale score is 10 or higher; b) feeling of not having rested; and c) obesity (women, body mass index >25.9 kg/m² (25-26); men, body mass index >27.9 kg/m² (27-28). This model gave an efficiency of 77.7%, a sensitivity of 61.9%, and a specificity of 91.6%.

Calculation of Costs

Costs were calculated based on a theoretical population of 1000 people using the following characteristics of home polygraphy, with the selected cutoff points and the previously calculated costs per test: prevalence of the disease 46.6% (prevalence obtained in our study population); diagnostic threshold, an RDI lower than 7.2 indicates that SAHS is not present; treatment threshold, an RDI greater than or equal to 13.7 indicates presence of SAHS. Between these values lies an uncertain area in which it would be necessary to carry out polysomnography. In order to calculate FPCs, we took into consideration the added cost of using CPAP in patients who were incorrectly diagnosed with SAHS by home polygraphy, and for the FNCs, we assumed that they would be mild or positional SAHS, which could be resolved by improving personal health and diet; therefore, these would not represent an additional treatment cost (cost=€0). Although it was not necessary in this study to repeat the home polygraphy recording, the possibility that 1.6% of home polygraphy recordings would have to be repeated was taken into consideration for the calculation of costs in the theoretical population using sleep unit data from the year 2003.

When the costs of performing polysomnography and home polygraphy in this theoretical population were calculated, the difference was –€32 339.80 for 1000 patients (Table 4). Therefore, carrying out home polygraphy in a patient with suspected SAHS represents a saving of €32.30 over polysomnography, even when polysomnography has to be used in cases of uncertain home polygraphy recordings or home polygraphy must be repeated when the first one is invalid, and assuming the additional expense of false positives treated with CPAP after diagnosis by home polygraphy.

Discussion

Studies evaluating respiratory polygraphy have been carried out using different systems and methods, although

| Points Selected on the Receiver Operator Characteristic Curve |
|---------------|-------------------|------------------|-------------------|-------------------|-------------------|
| **Cutoff Point** | **RDI** | **Efficiency, %** | **Sensitivity, %** | **Specificity, %** | **PPV, %** | **NPV, %** |
| AHI≥10          | Efficient (FPC=1; FNC=1) | 11.6 | 82.2 | 71.4 | 91.7 | 88.2 | 78.6 |
|                | Sensitive (FPC=1; FNC=1)  | 7.2  | 71.1 | 90.5 | 54.2 | 63.3 | 86.7 |
|                | Specific (FPC=1; FNC=1)   | 13.7 | 80 (67-92)* | 61.9 (38-85)* | 95.8 (85-100)* | 92.9 (75-100)* | 74.2 (57-91)* |
|                | Efficient (FPC=2; FNC=1)  | 13.7 | 80 | 61.9 | 95.8 | 92.9 | 74.2 |
| AHI≥10 + EEpworth≥10 | Efficient (FPC=1 FNC=1) | 13.7 | 79.5 | 60 | 95.8 | 92.3 | 74.2 |

Abbreviations: AHI, apnea–hypopnea index; FNC, false negative cost; FPC, false positive cost; NPV, negative predictive value; PPV, positive predictive value; RDI, respiratory disturbance index.

*The 95% confidence interval is shown in parentheses.
very few have been carried out in the patient’s home.16-19,24,25 In the present study, which validated the Edentec Monitoring System in the patient’s home in comparison with the gold standard (polysomnography), home polygraphy was observed to be efficacious and efficient as a diagnostic method in the population studied. Cutoff points were established for home polygraphy with suitable sensitivity, specificity, and positive and negative likelihood ratios, thus rendering it useful when making a diagnosis and prescribing therapy.

A diagnosis of SAHS is based on clinical and polysomnographic criteria. The variability of clinical symptoms—also found in this study—and the fact that we included patients with clinically suspected SAHS referred from primary care, and later from the pulmonology outpatient clinic, mean that these patients were very carefully selected, with a high probability of presenting SAHS, as shown by the prevalence we observed (46.6%). Therefore, the value of a clinical diagnosis is small by the time these patients reach the sleep unit, due to the fact that it has been “used up along the way,”23 as can be seen from the poor contribution of clinical diagnosis in the logistic regression model constructed and evaluated in this study.

The random sampling of patients avoids possible selection bias and enables us to obtain a representative sample of the population attended at our sleep unit, which works in much the same way as other specialized referral units in Spain.

The differences in means were significant between the pre-HP and pre-PSG studies with regard to the number of total respiratory events. As the studies were carried out on 2 different nights, we must allow for night-to-night variability. This has been observed elsewhere, even with standard polysomnography.26 We also found statistically significant differences in the desaturation index, mean SpO₂, and percentage of time with an SpO₂ less than 90%.

In these cases, although night-to-night variability may have some effect, we must remember that whereas polysomnography enables us to distinguish between sleep and wakefulness, home polygraphy does not. Therefore, polysomnography values refer to sleep time, whereas home polygraphy values refer to the total study time, including time awake. SpO₂ is always greater when the patient is wakeful; during sleep, mainly during REM sleep,27 there is a fall in SpO₂. Thus, these desaturations could be underestimated during home polygraphy recording, as the test does not differentiate between sleep and wakefulness. The same is true of heart rate.

Some of the validation studies carried out in the home have used the Edentec Monitoring System;16,18; these studies found a 0.9 agreement16 and sensitivities and specificities that varied according to the RDI cutoff point chosen (between 63% and 95% and between 33% and 93%, respectively).18 Other home monitoring studies using systems different from ours found sensitivities ranging from 78% to 94% and specificities ranging from 41% to 92%.17,19 Therefore, our results can be compared with those published in the literature on the validation of respiratory polygraphy systems in the patient’s home, both with the Edentec Monitoring System and with other systems.

The Edentec Monitoring System was not validated simultaneously in the sleep laboratory because it has been validated elsewhere16 and because the main objective of our study was to use respiratory polygraphy in the patient’s home. It is not the same to use a test for screening as for diagnosis and application of treatment. In our population,
we needed a specific test that would not produce a large number of false positives—that is, patients diagnosed with SAHS who do not present the illness—and in whom treatment is, consequently, inappropriate, leading to an increase in costs. By selecting a specific test, we accepted the possibility of a greater number of false negatives, considering that the SAHS would be mild and could be resolved by measures to improve personal health and diet and that they would not lead to an increase in costs or deprive the patient of suitable treatment. In this sense, we obtained greater specificity by considering FPCs as double the FNCs (FPC = 2; FNC = 1), with an RDI greater than or equal to 13.7 as the most efficient cutoff point. This cutoff point was the same as the one we obtained if we took as a diagnostic criterion of SAHS an AHI of 10 or more, a score of 10 or more on the Epworth Sleepiness Scale, and a similar FPC and FNC.

We calculated diagnostic probabilities and found that a patient who attended our unit had a pretest probability of presenting SAHS of 46.6%: if home polygraphy gave an RDI of less than 7.2 (sensitive cutoff point), the posttest probability of presenting SAHS would fall to 13.6%, and if the result was positive, that is, an RDI greater than or equal to 13.7 (specific cutoff point), the posttest probability of having SAHS would be 92.8%. It was not necessary to repeat the home polygraphy recording and there were no cases of invalid data, mainly because, in our study, the respiratory polygraphy device was connected by a sleep unit technician in the patient’s home, unlike in other studies, in which the patient fitted the system at home.

There were discrepancies between home polygraphy and polysomnography in 6 patients. All 6 would have been in the uncertain area (7.2>RDI<13.7), had mild SAHS and events when in supine decubitus, and were false negatives who would have had to adopt measures to improve personal health and diet. Therapy would have been changed in only 2 of these 6 patients: 1 due to daytime somnolence and the other due to cardiovascular risk factors.

We carried out a cost analysis using a diagnostic algorithm that included home polygraphy. We took into account the costs not only of the necessary disposable material but also of the time taken by medical personnel and sleep unit technicians. Home testing does not involve an increase in costs; by contrast, in this study, it would save €32.30 per patient. In cost analysis studies, home polygraphy represents savings compared with polysomnography, although in none of the previous studies were FPCs taken into account.

In our opinion, the most important limitation of this study is the possible selection bias—only patients with suspected SAHS were studied and not the general population; therefore, a cutoff point with high specificity was sought in the analysis.

In summary, we show that home polygraphy is an effective method for the diagnosis of SAHS that can be carried out in the patient’s home and does not lead to an increase in cost. We must stress that use of this technique makes diagnosis of SAHS easier outside the organizationally and technologically complicated sleep unit. Therefore, this technique should be included in all pulmonology services.

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