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Diagnosis of Obstructive Sleep Apnea Syndrome and Its Outcomes With Home Portable Monitoring*

Ana Claudia Tonelli de Oliveira, MD, MSc; Denis Martinez, MD, PhD; Luiz Felipe T. Vasconcelos, MD; Sandro Cadaval Gonçalves, MD, PhD; Maria do Carmo Lenz, MD, PhD; Sandra Costa Fuchs, MD, PhD; Miguel Gus, MD, PhD; Erlon Oliveira de Abreu-Silva, MD; Leila Beltrami Moreira, MD, PhD; and Flávio Danni Fuchs, MD, PhD

Background: The use of portable respiratory monitoring (PM) has been proposed for the diagnosis of obstructive sleep apnea syndrome (OSAS), but most studies that validate PM accuracy have not followed the best standards for diagnostic test validation. The objective of the present study was to evaluate the accuracy of PM performed at home to diagnose OSAS and its outcomes after first validating PM in the laboratory setting by comparing it to polysomnography (PSG).

Methods: Patients with suspected OSAS were submitted, in random order, to PM at the sleep laboratory concurrently with PSG (lab-PM) or at home-PM. The diagnostic performance was assessed by sensitivity, specificity, positive and negative predictive values, positive likelihood ratio (+LR), negative likelihood ratio (−LR), intraclass correlation coefficients, κ statistic, and Bland-Altman plot.

Results: One hundred fifty-seven subjects (73% men, mean age ± SD, 45 ± 12 yr) with an apnea-hypopnea index (AHI) of 31 (SD ± 29) events/h were studied. Excluding inadequate recordings, 149 valid comparisons with lab-PM and 121 with unattended home-PM were obtained. Compared to PSG for detecting AHI > 5, the lab-PM demonstrated sensitivity of 95.3%, specificity of 75%, +LR of 3.8, and −LR of 0.11; the home-PM exhibited sensitivity of 96%, specificity of 64%, +LR of 2.7, and −LR of 0.05. Kappa statistics indicated substantial correlation between PSG and PM results. Bland-Altman plot showed smaller dispersion for lab-PM than for home-PM. Pearson product moment correlation coefficients among the three AHIs and clinical outcomes were similar, denoting comparable diagnostic ability.

Conclusions: This study used all available comparison methods to demonstrate accuracy of PM in-home recordings similar to that of repeated PSGs. PM increases the possibility of correctly diagnosing and effectively treating OSAS in populations worldwide.

(CHEST 2009; 135:330–336)

Key words: diagnosis; home monitor; obstructive sleep apnea syndrome

Abbreviations: AHI = apnea-hypopnea index; BMI = body mass index; CI = confidence interval; CPAP = continuous positive airway pressure; ESS = Epworth Sleepiness Scale; LR = likelihood ratio; OSAS = obstructive sleep apnea syndrome; PM = portable respiratory monitoring; PSG = polysomnography; ROC = receiver operating characteristic; SaO2 = arterial oxygen saturation
The Portable Monitoring Task Force\textsuperscript{12} mentioned lack of published information on safety, ease of use, reliability, durability, economy, and diagnostic accuracy. Validation studies\textsuperscript{6,13–17} of these monitors have been conducted, but most lack either laboratory or home recordings and comprise a small number of subjects. Hence, the purpose of the present study is to provide information regarding the diagnostic accuracy of a type 3 PM in the laboratory and at home, taking PSG as the “gold standard,” in a large number of patients with suspected OSAS.

**Materials and Methods**

**Research Subjects**

Consecutive patients $>18$ years of age who were referred for evaluation of suspected OSAS were invited to participate in the study if they signed the informed consent form. Pregnant women, patients with severe comorbidities (cancer, heart failure, etc) or difficulties that would interfere with the examinations, and patients residing outside the metropolitan area of Porto Alegre (Rio Grande do Sul, Brazil) were excluded. This study was approved by the Ethics Committee of our institution.

**Study Protocol**

The sleep studies were carried out in the laboratory and at home on two different nights and with a maximum interval of 48 h. In the laboratory, the subjects underwent PSG and PM (lab-PM) study simultaneously. The technicians were allowed to intervene in both the studies in the case of technical issues. For the home study (home-PM), the equipment was handed out to the subjects, who were instructed on its use. On the following day, subjects returned the equipment, and the data were read by specific software.

Anthropometric data and BP were measured just before the PSG study. Each subject completed a survey questionnaire that included the Epworth Sleepiness Scale (ESS), the Berlin Questionnaire for sleep apnea, medical history, and regular use of medicines. The PM data were manually interpreted in a satellite location by one of the authors, who was unaware of the subjects’ PSG results. The PSG results were interpreted at the laboratory by another author, who is a board certified sleep specialist.

**PSG**

All subjects submitted to nocturnal PSG, which was carried out according to the following standard methods: EEG (C3-A2, C4-A1), electrooculogram (left eye and right eye), submental and anterior pretilial electromyograms and ECG. Airflow was measured by a nasal cannula attached to a pressure transducer through a Y tube to allow connection to the pressure port of the PM on the lab-PM night. Arterial oxygen saturation ($\text{SaO}_2$) was measured by a pulse oximeter. Sleep staging was performed using Rechtschaffen and Kales criteria.\textsuperscript{18}

**Portable Monitoring**

Portable monitoring was performed as previously described\textsuperscript{10} using Somnocheck (Weinmann GmbH, Hamburg, Germany), a type 3 monitor with position sensor, pressure transducer, and pulse oximeter. The unit was adjusted to the subject’s chest using a belt, and the nasal cannula was used to record airflow and snoring. The pulse oximeter recorded both oxygen saturation and heart rate. Alarms for oximeter and flow signal loss were left on. For the lab-PM, a technician could help the subject when the PM alarms sounded. For the home-PM, the subjects were instructed on how to wear the equipment as well as on how to relocate the sensors if the lost signal alarm sounded. Recordings shorter than 4 h of artifact-free tracings were discarded.

**Event Definition**

For both PSG and PM, apneas, hypopneas, and the apnea-hypopnea index (AHI) were defined according to standard criteria.\textsuperscript{20} The PSG AHI was considered as the reference variable for the OSAS diagnostic definition. The PM AHI was defined as the total number of apneas and hypopneas divided by the number of hours of artifact-free recording. Information from the sleep diary and position recording were used to exclude stretches of the recording in which wakefulness was indirectly deduced. Severity of OSAS was categorized as follows: mild, AHI = 5 to 15 events/h; moderate, AHI = 15 to 30 events/h; and severe, AHI > 30 events/h.\textsuperscript{20}

**Statistical Analysis**

Continuous variables are described as mean $\pm$ SD. AHI results were log transformed for most analyses. The accuracy of PM was described by sensitivity, specificity, positive and negative predictive values, positive likelihood ratio (+LR), and negative likelihood ratio (−LR). Concordance between PM and PSG results was assessed by receiver operating characteristic (ROC) curve analyses, intraclass correlation coefficient, $\kappa$ statistic, and the limits on the Bland-Altman plot. Bland-Altman concordance analysis was performed using logarithmic transformation, as recommended by the authors.\textsuperscript{21} A probability of $\alpha$ error $<5\%$ was considered significant.

**Results**

Two hundred and twenty patients were invited to participate in the study between November 2004 and August 2006. One hundred and sixty-three consented, and 157 underwent PSG and were included.
in the analysis. Figure 1 shows a diagram of the subject recruitment flow. The 57 patients who did not consent to participate in the study were similar to the analyzed population in terms of age, gender, body mass index (BMI), and BP.

Data from the lab-PM were lost for eight (6%) subjects as follows: six had < 4 h of recording due to battery failure, one lost the airflow signal, and one lost the oximetry signal. Thirty-six (23%) subjects were excluded from the home-PM analysis for several reasons. Thirteen (8%) did not retrieve the equipment from the laboratory in order to undergo the home-PM and were excluded from the home-PM analysis. Considering the 144 subjects who underwent home-PM, the data-loss rate due to technical problems was 16%. Twelve (8%) subjects had < 4 h of artifact-free recordings, mostly because of battery failure; five (3%) lost oximetry signal; four (3%) lost airflow recording; one (1%) could not tolerate the equipment; and one (1%) forgot to wear the equipment (Fig 1). The 16% rate of data loss in home-PM is significantly larger than the 5% seen in the lab-PM ($\chi^2 = 9.6; p = 0.002$). The excluded subjects were similar to those who were included in terms of anthropometric and PSG variables.

The subject characteristics and study variables are shown in Table 1. The number of subjects included in the comparisons between lab-PM with PSG and home-PM with PSG was restricted to the examinations done in both conditions. The time spent in supine position was similar at home and in the laboratory ($p = 0.05$). For a PSG AHI $\geq 5$, the OSAS prevalence in study subjects was 87%. Table 2 shows the statistics values and its 95% confidence intervals (CIs) between the PSG AHI and lab-PM and home-PM AHI. The intraclass correlation coefficient between lab-PM AHI and home-PM AHI was 0.90 (95% CI, 0.86 to 0.93).

Table 3 presents the sensitivity, specificity, predictive values, area under the ROC curve, best cut point, and likelihood ratios of home-PM for the different OSAS classification levels. The probability of home-PM to correctly exclude the OSAS was 91.7% and to correctly diagnose severe OSAS, 87.6%.

Although performed under the same conditions as PSG, the diagnostic performance of the lab-PM was,
in general, only marginally higher than that of the home-PM compared to PSG. For instance, the sensitivity of lab-PM to detect an AHI < 5 was 95.3% (95% CI, 91.7 to 99.0), and the specificity was 75% (95% CI, 56 to 94); the sensitivity of the home-PM was 96.1% (95% CI, 92.5–99.8), and the specificity was 64.7% (95% CI, 42.3–87.4). The best AHI cut points were 6 for lab-PM and 7 for home-PM. At these cut points, the +LR and −LR for lab-PM were 3.8 and 0.11, respectively, and the +LR and −LR for home-PM were 2.7 and 0.05, respectively.

The Bland-Altman concordance analysis demonstrated relatively small dispersion for lab-PM compared with PSG (Fig 2). The limits ranged from −8 to 9.2 events/h. Home-PM was performed with different equipment, on different days, and at separate locations and showed larger limits (range, −18 to 22 events/h) compared to PSG.

Several clinical outcomes obtained from the Berlin Questionnaire for sleep apnea and the ESS as well as from systolic and diastolic BP were correlated with PSQ AHI and home-PM AHI (Table 4). All Pearson product moment correlation coefficients were similar, indicating that the diagnostic ability of the three indexes is comparable.

**Discussion**

In this study, a type 3 PM was tested for its ability to diagnose OSAS at home and was simultaneously validated against the laboratory “gold standard” in a large sample of patients with clinically suspected OSAS, which represents the spectrum seen in clinical practice. The order of the examinations done in the laboratory or at home was randomly assigned. The results show that the accuracy of home-PM compared with PSG is within the limits usually seen when two diagnostic tools are compared. Our results are similar to those reported by other authors \(^{17,22,23}\) in studies using smaller samples or alternative PM study methods not validated in the laboratory.

Conservative estimates suggest that about 2,310 PSG studies per 100,000 patients per year would be necessary to diagnose moderate to severe OSAS, exceeding the current capacity of most countries to perform PSG studies by tenfold.\(^{24}\) The scarce availability and high cost of PSG also support the use of simpler validated instruments as a first step toward diagnosis.

In our study, the best performance of PM was at the extremes in subjects with AHI > 30 or AHI < 5. The +LR of PSG AHI > 30 was 10.1 for home-PM AHI > 30. Additionally, when the home-PM AHI is < 5, the −LR indicates a twentyfold lower probability of having PSG AHI > 5. The \(\kappa\) statistic and Bland-Altman plot pointed in the same direction. This performance of the home-PM is clinically interesting because it can detect which patients either urgently require treatment or can be reassured that continued treatment is unnecessary. The ruling-in or ruling-out approach of an accurate screening tool also may be important in the evaluation of highly prevalent associated conditions, such as hypertension, where an investigation for OSAS has been recommended in the cases with hypertension resistant to treatment.\(^{25}\) We\(^{19}\) have previously shown that OSAS diagnosed by home-PM was strongly associated with resistant hypertension, confirming that this method is capable of detecting the presence of disordered breathing associated with comorbidities. The \(\kappa\) statistic analysis indicated substantial agreement between home-PM and PSG, and the Bland-Altman plot showed graphic evidence of adequate concordance between these diagnostic methods. The variability between the two methods could be due to

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**Table 2—Kappa Statistic Analysis To Assess Concordance Among PSG, Lab-PM, and Home-PM**

<table>
<thead>
<tr>
<th>OSAS Classification by PSG</th>
<th>Lab-PM</th>
<th>Home-PM</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHI &lt; 5</td>
<td>0.69 (0.52–0.84)</td>
<td>0.64 (0.46–0.81)</td>
</tr>
<tr>
<td>AHI ≥ 5 to &lt; 15</td>
<td>0.51 (0.35–0.67)</td>
<td>0.37 (0.20–0.55)</td>
</tr>
<tr>
<td>AHI ≥ 15 to &lt; 30</td>
<td>0.55 (0.4–0.71)</td>
<td>0.38 (0.20–0.55)</td>
</tr>
<tr>
<td>AHI ≥ 30</td>
<td>0.79 (0.63–0.95)</td>
<td>0.73 (0.55–0.90)</td>
</tr>
<tr>
<td>Overall</td>
<td>0.64 (0.55–0.74)</td>
<td>0.53 (0.42–0.63)</td>
</tr>
</tbody>
</table>

\(^*p < 0.001\) for all values.

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**Table 3—Sensitivity, Specificity, Predictive Values, Area Under the ROC Curve, Best Cut Point for PM AHI, and Likelihood Ratio of AHI Measured by Home-PM for the Different OSAS Classification Levels**

<table>
<thead>
<tr>
<th>OSAS Classification by PSG</th>
<th>Sensitivity, % (95% CI)</th>
<th>Specificity, % (95% CI)</th>
<th>Positive Predictive Value, %</th>
<th>Negative Predictive Value, %</th>
<th>Area Under ROC Curve (95% CI)</th>
<th>Best Cut Point</th>
<th>+LR/−LR</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHI ≥ 5</td>
<td>96.15 (92.5–99.8)</td>
<td>64.7 (42.0–87.4)</td>
<td>94.3 (89.9–98.7)</td>
<td>73.3 (51.0–95.7)</td>
<td>0.96 (0.91–0.99)</td>
<td>7</td>
<td>2.7/0.05</td>
</tr>
<tr>
<td>AHI ≥ 10</td>
<td>90.7 (82.7–95.2)</td>
<td>82.9 (67.3–91.9)</td>
<td>92.9 (85.3–96.7)</td>
<td>68.4 (62.8–88.6)</td>
<td>0.92 (0.85–0.96)</td>
<td>9</td>
<td>5.2/0.11</td>
</tr>
<tr>
<td>AHI ≥ 15</td>
<td>81.3 (71.1–85.8)</td>
<td>82.6 (69.3–90.9)</td>
<td>88.4 (78.8–94.0)</td>
<td>73.1 (59.7–83.2)</td>
<td>0.91 (0.85–0.96)</td>
<td>9</td>
<td>4.6/0.22</td>
</tr>
<tr>
<td>AHI ≥ 30</td>
<td>80.0 (68.3–91.7)</td>
<td>92.1 (86.0–99.2)</td>
<td>85.7 (75.1–96.3)</td>
<td>85.6 (81.6–95.6)</td>
<td>0.92 (0.86–0.96)</td>
<td>33</td>
<td>10.1/0.21</td>
</tr>
</tbody>
</table>
differences in the equipment and the scorers. Regarding hypopneas, evidence supports that minor differences in detection equipment can lead to rejection or acceptance of an event. Even when the equipment is the same, the AHI from the full PSG exceeds that derived from flow and oximeter signals by almost 6 events/h.27 The oximeter response time and averaging time can have a significant effect on the number of hypopneas counted.25,29 Because desaturation was a criterion for hypopnea scoring in the present study, the difference in oximeter performance alone could explain the different AHIs in the same night. In addition, Collop30 has shown that the same PSG can produce diverse results when scored by several technicians. Therefore, the bias of 1 event/h in the present study is surprisingly low when the mean PSG and lab-PM results are compared.

The PSG and home-PM studies on different nights showed a similarly low bias and an AHI variation of −18 to 22 events/h. The higher dispersion between the results of the examinations performed at home and with the PSG were expected because this phase of the experiment adds the following three causes of variability: montage change, environment change, and true night-to-night variability. In the Sleep Heart Health Study,31 the night-to-night variability between laboratory PSG and home PSG was similar to what we found. The influence of different patients' sleeping position on AHI results is long known.32,33 In the laboratory, our subjects spent an average of 240 min in supine position, whereas at home they spent an average of 219 min, exactly the same percentage of the artifact-free recording time. This finding, therefore, cannot explain the higher AHI at home.

The variability of the present results are inside the range already reported by other authors and are similar to those found that compare repeated PSG studies. Analyzing four consecutive full-night PSG studies, Bittencourt et al35 reported an AHI bias between the first and third night, as evidenced by

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Table 4—Pearson Product Moment Correlation Coefficients and p Values for the Correlations Between Several Clinical Outcomes, Including Questions of the Berlin Questionnaire and AHIs in the Laboratory and at Home*

<table>
<thead>
<tr>
<th></th>
<th>PSG AHI</th>
<th>Lab-PM AHI</th>
<th>Home-PM AHI</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI</td>
<td>.453 (.000)</td>
<td>.481 (.000)</td>
<td>.458 (.000)</td>
</tr>
<tr>
<td>Systolic BP</td>
<td>.280 (.000)</td>
<td>.305 (.000)</td>
<td>.303 (.001)</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>.175 (0.028)</td>
<td>.179 (0.029)</td>
<td>.249 (0.006)</td>
</tr>
<tr>
<td>Do you snore?</td>
<td>.200 (0.012)</td>
<td>.203 (0.025)</td>
<td>.203 (0.025)</td>
</tr>
<tr>
<td>Snoring loudness</td>
<td>.344 (.000)</td>
<td>.354 (.000)</td>
<td>.305 (.001)</td>
</tr>
<tr>
<td>Snoring frequency</td>
<td>.252 (.001)</td>
<td>.235 (.004)</td>
<td>.229 (.012)</td>
</tr>
<tr>
<td>Does your snoring bother other people?</td>
<td>.258 (.001)</td>
<td>.253 (.002)</td>
<td>.218 (.016)</td>
</tr>
<tr>
<td>How often have your breathing pauses been noticed?</td>
<td>.411 (.000)</td>
<td>.379 (.000)</td>
<td>.387 (.000)</td>
</tr>
<tr>
<td>Are you tired after sleeping?</td>
<td>.047 (0.557)</td>
<td>.025 (0.765)</td>
<td>.094 (0.308)</td>
</tr>
<tr>
<td>Are you tired during wake time?</td>
<td>.052 (0.516)</td>
<td>.051 (0.536)</td>
<td>.102 (0.267)</td>
</tr>
<tr>
<td>Have you ever fallen asleep while driving?</td>
<td>.330 (0.000)</td>
<td>.274 (0.001)</td>
<td>.188 (0.039)</td>
</tr>
<tr>
<td>Do you have high BP?</td>
<td>.151 (0.059)</td>
<td>.187 (0.023)</td>
<td>.126 (0.167)</td>
</tr>
<tr>
<td>ESS</td>
<td>.231 (.004)</td>
<td>.240 (.003)</td>
<td>.184 (.044)</td>
</tr>
<tr>
<td>SaO2min, PSG</td>
<td>−.711 (.000)</td>
<td>−.714 (.000)</td>
<td>−.706 (.000)</td>
</tr>
<tr>
<td>SaO2min, home</td>
<td>−.621 (.000)</td>
<td>−.696 (.000)</td>
<td>−.656 (.000)</td>
</tr>
</tbody>
</table>

*Bold type indicates significance (p < 0.05).
Bland-Altman plot, of 1.45 events/h, varying from –22.4 to 25.3 events/h. In our study, PSG and home-PM were performed on different nights, at separate places, and with distinct equipment. The comparison, however, shows that the scatter of AHI results in the Bland-Altman plot has lower variability than the night-to-night variability described by Bittencourt et al. Most problems initially happened due to home-PM is high but within the reported range of 3 to 18%.12 Most problems initially happened due to inexperience in instructing the patients and in verifying the battery’s status. Focusing on avoiding these problems can reduce data loss.

Evidence regarding unattended monitoring is incomplete in several domains.12 The present study can help to fill the knowledge gaps. First, many published studies, used type 3 equipment that have not been validated by comparison to a standard, such as PSG. Second, in most cases equipment were validated in small assisted-environment studies. Third, most studies involved small numbers of patients.23,36–38 The number of subjects evaluated in the present study is greater than most of the studies that used type 3 monitors published thus far and is, to our knowledge, the largest that assesses home-PM detection of OSAS.

The clinical outcomes of OSAS shown in Table 4 were uniformly correlated with PSG AHI and home-PM AHI. These findings are encouraging because they indicate that the diagnostic ability of the two methods is comparable. We have previously shown that OSAS diagnosed by home-PM was strongly associated with resistant hypertension, confirming that this method is capable of detecting the presence of disordered breathing, which is associated with comorbidities. Whitelaw et al randomized patients to have either PSG or home oximetry testing before using continuous positive airway pressure (CPAP) and showed no superiority of PSG over home oximetry in terms of improved quality of life with treatment. Accordingly, Mulgrew et al found no advantage of a PSG study group over an ambulatory group (home monitoring and auto-CPAP) on 3 weeks of treatment with automatic positive airway pressure (APAP) device with regard to AHI results, ESS results, and quality of life but found a small advantage on adherence of treatment in the ambulatory group.

CONCLUSIONS

After being validated at the laboratory against full PSG, the diagnostic performance of a type 3 PM for detecting OSAS at home is within acceptable limits for diagnostic tests. The agreement of home-PM with PSG is similar to that described between two typical PSG studies. These results suggest that the availability of PM will increase the possibility of correctly diagnosing and effectively treating sleep breathing disorders in populations worldwide.

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33 George CF, Millar TW, Kryger MH. Sleep apnea and body position during sleep. Sleep 1988; 11:90–99
Erratum: Chest 2008; 133:62–71

In the January 2008 issue, in the article by Lucangelo et al., titled “Prognostic Value of Different Dead Space Indices in Mechanically Ventilated Patients With Acute Lung Injury and ARDS” (Chest 2008; 133:62–71), the correct affiliation for Lluis Blanch, should be as follows: Lluis Blanch, MD, PhD; Critical Care Centre; CIBER Enfermedades Respiratorias: Hospital de Sabadell; Corporació Parc Taulí: Sabadell.


In the January 2009 issue, in the article by Langdon-Neuner titled “When Does Previous Disclosure Become a Prior Publication?” (Chest 2009; 135:233–237), the last sentence of the first full paragraph on page 234, the sentence should read, “Press reports of meetings are also not precluded, but additional data or copies of tables should not amplify such reports.”

Erratum: Chest 2009; 135:276–286

In the February 2009 issue, in the article by Lellouche et al., titled “Humidification Performance of 48 Passive Airway Humidifiers” (Chest 2009: 135:276–286), in Table 1, the manufacturer of Device Nos. 1 and 3 should be listed as Medisize.


In the February 2009 issue, in the article by Tonelli de Oliveria et al., titled “Diagnosis of Obstructive Sleep Apnea and Its Outcomes with Home Portable Monitoring” (Chest 2009; 135:330–336), the name of the third author is misspelled. It should be Luiz Felipe Teer-Vasconcellos.
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