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ORIGINAL ARTICLE

Sleep Science

Quality of an ambulatory monitoring technique for diagnosing obstructive sleep apnea under conditions of limited resources

María del Cármen Hernández-Bendezú[1]
María Yolanda Arias-Peña[1]
Martha Guadalupe Torres-Fraga[1]
José Luis Carrillo-Alduenda[1]

[1] National Institute of Respiratory Diseases, Sleep Medicine Unit - Mexico - Mexico City - Mexico.

ABSTRACT

Objectives: To: 1) evaluate the quality of an ambulatory monitoring technique for diagnosing Obstructive Sleep Apnea Syndrome (OSAS) while patients move through the city; and 2) identify factors that lead to data loss. **Methods:** Clinical histories were reviewed and ambulatory portable monitorings of adults with high pretest probability for OSAS were included, the signals monitored were pulse oximetry, heart rate, nasal pressure, snoring, chest band and body position. The equipment was connected from 14:00-20:00 h and then patients moved through the city turning it off and on at home. Results were analyzed visually to record all the minutes lost. A good-quality study was defined as recording time 240 min and signal loss <20%. A cost/benefit analysis was performed using Golpe et al.`s methodology. **Results:** A total of 70 recordings were analyzed. Most subjects were obese men with severe OSAS. Signal quality was determined to be good with a median signal loss of 4.9 min (0-405) that represented 1% (0-99) of total recording time. The signal lost most often was pulse oximetry at 1.8 min (0-403, p=0.0001). Of the 70 studies performed, 57 (81%) met the definition of good quality, while 13 (19%) had to be repeated. Men lost the pulse oximetry signal more often than women. This technique could represent savings of 65-75%. **Conclusions:** Placing a portable OSAS monitor during the day while patients move around the city turning it on and off at home does not affect the quality of the study results obtained and is a cost-effective method.

Keywords: Sleep Apnea; Obstructive; Polysomnography; diagnosis.

Corresponding author: José Luis Carrillo-Alduenda. National Institute of Respiratory Diseases - Sleep Medicine Unit - México. Calzada Tlapan 4502, Pabellón 9, Col. Sección XVI, CP 14080. E-mail: jlcarrillo14@hotmail.com
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INTRODUCTION

Obstructive Sleep Apnea Syndrome (OSAS) is a significant public health problem, due not only to its high prevalence[1], but also because of its elevated health costs[2] and the diverse damage and complications it causes[3].

The standard diagnostic tool for OSAS is polysomnography (PSG)[4], but this method is expensive, technically complicated and of limited availability in our region. An alternative approach that is low-cost and readily accessible consists in studying patients using a portable monitor (simplified monitor, ambulatory monitoring or type 3 monitor)[5], though this requires training the patient to use it correctly, or having specialized technicians install the device in the patient's home, which entails certain consequences; *i.e.*, higher cost, risks to personnel during transport, and/or loss of study data due to inadequate handling of the equipment[6].

The Sleep Medicine Unit at Mexico's National Institute of Respiratory Diseases (INER, acronym in Spanish) lacks the personnel needed to install devices in patients' homes, so in special cases of disease severity and a high risk of complications, we have placed portable monitors (PM) at the hospital and sent patients to sleep at home in an effort to avoid data loss due to inadequate handling of the device. This means that patients move through Mexico City with the sensors attached and should turn the device on and off at home. This diagnostic strategy allows our medical service to perform advanced studies and more diagnostic tests with no additional resources; however, the signal quality obtained using this strategy has not been evaluated.

Therefore, the objective of the present study was to evaluate the quality of the signals obtained from these portable monitors in terms of diagnosing OSAS, as a sample of patients moved through Mexico City with the monitor in place and to identify factors associated with data loss.

MATERIALS AND METHODS

The study was approved by the INER's Committees on Science and Bioethics in Research (no. C54-17). Clinical histories available at this service covering the period from May 1, 2012, to May 31, 2017, were reviewed, including all PM studies performed at the homes of adult patients with high pre-test probability of suffering OSAS and without significant comorbidities. Those studies were conducted with a Stardust II® monitor (Philips Respironics) that measures: pulse oximetry, heart rate, flow through nasal pressure cannula, snoring, respiratory movement by a piezoelectric chest band, and body position. The monitor was connected between 14:00 and 20:00 h by trained personnel as follows:

1. The nasal pressure cannula was placed on the nose around the auricular pavilions, adjusted over the chin and attached with tape on both cheeks.
2. The respiratory movement band was placed on the thorax at the level of the armpit and adjusted to leave a clearance of 2 fingers.
3. A multi-site pulse oximeter was placed on the second finger of the non-dominant hand and attached with four strips of tape (1 along the finger, 2 around the distal and proximal areas, and one on the back of the hand).
4. The recorder was placed on the mid-sternal region; held in place by a cord around the neck and the thorax band.
5. Signals were verified according to the manufacturer's specifications.
6. Patients were instructed how to turn the device on and off correctly.
7. Patients were then sent home from the Sleep Medicine Unit with the device connected and they were instructed to turn the PM on at bedtime and turn it off until the awakening.

Polygraphs were scored manually following current rules[7]. Hypopnea was defined as a drop ≥30% in the nasal pressure cannula accompanied by a desaturation ≥3%.

All studies were examined visually, and the number of minutes lost from each signal type were recorded manually. Signal loss was defined as the absence of a signal on the screen. Because snoring was processed as a vibration of the flow signal extracted from the nasal pressure cannula, it was excluded from the analysis. Because pulse oximetry and heart rate were obtained from the same sensor, those data were analyzed together. The percentage of data lost for each signal was calculated as follows: % of data lost = minutes of signal loss X 100 / minutes recorded. Good quality studies were defined as those that had a total recording time of at least 240 minutes (4 hours) with signal loss <20%, this definition was adjusted by the median cardio-respiratory signal loss from the Sleep Heart Health Study (SHHS)[8].

Data were summarized as medians (minimum-maximum) or frequency, according to type. The U Mann Whitney test was applied to compare continuous variables, while multiple comparisons were performed with a Kruskal-Wallis test, when differences were found a Student's t test was conducted. Correlations among continuous variables were evaluated by Spearman's Rho; the significance level was set at $p<0.05$. The STATA 12 statistical package was utilized.

To evaluate the direct cost (expressed in U.S. dollars) of this technique of at-home sleep study from the perspective of our Center, and compare it to PM performed in the hospital and a supervised PSG procedure, we applied the methodology described by Golpe et al.[9].

1. For a supervised PSG, the cost of using the device was obtained by dividing the value of the polysomnography equipment (54,505.35 USD) by the number of sleep studies that can be made during its lifetime (assuming a period of 5 years and 312 studies per year, in our unit PSG is performed 6 nights

per week) plus the per-study cost of consumables and the use of Center´s installations. To calculate the cost of realization we consider the monthly salary of a sleep technician divided by the number of PSG that he/she performs per month. The cost of scoring the study was estimated assuming 3 hours of a sleep nurse's time.

2. In the case of PM performed at the hospital, the value of the equipment ($6,972.52 USD) was divided by the number of sleep studies that could be performed during its lifetime (assuming a period of 5 years and 312 studies per year, working 6 nights per week), plus the per-study cost of consumables and the use of the Center's installations. To account for the cost of the technician required to conduct testing, her/his monthly salary was divided by the number of PM per month. An estimated 1 hour of the salary of a sleep nurse was included for scoring the test.
3. For at-home PM, the cost for equipment use was taken as the value of the device ($6,972.52 USD) divided by the number of sleep studies that could be carried out during its lifetime (assuming 5 years and 260 studies per year, as this format is only feasible from Monday-to-Friday), plus the cost of consumables per study and the use of the Center's installations. For technical costs, we calculated 1 h of the salary of a sleep technician plus the aforementioned cost for reading results. To consider lost and/or invalid studies, following the recommendations of the American Academy of Sleep Medicine[10], we decided that they should be handled as a second-stage supervised PSG. Thus, we calculated the cost of PSGs that would have to be performed for this group of patients in proportion to the number of PM that were repeated and then divided that figure by the total number of studies. Finally, we factored in the cost of the insurance policy required to use the device outside the hospital by dividing the total annual cost by the number of feasible studies per year.

RESULTS

Some of this information has been presented previously in the form of an abstract. Two operators carried out 70 studies using this format, all were included and none was negative por OSAS. Most patients were men with a median age of 60 years who were obese and had severe obstructive sleep apnea. Patient´s characteristics are shown in Table 1.

The quality of monitoring with this technique was determined to be good because the median signal loss was 4.9 minutes (0-405), which represents just 1% (0-99) of total recording time. The signal that was lost most often was pulse oximetry at 1.8 minutes (0-403.7, p=0.0001). A total of 57 recordings (81%) met the definition of a good quality study, while 13 (19%) had to be repeated, in all cases, a second home PM was performed with an adequate result. Because no loss of the signal from the position sensor was detected, it is not described in our results. No patient failed to turn on the device. Table 2 presents the data on signal loss.

Table 1. General characteristics of the sample.

Characteristics	Median	Min-Max
Gender (males)*	48	68
Age (years)	60	26-90
Epworth	15	11-24
BMI (kg/m^2)	32	25-40
Total recording time (minutes)	465	276-546
Time in supine position (minutes)	76.3	0.6-464.5
Time in non-supine position (minutes)	365.5	8.5-545
AHI (h^{-1})	44.5	7.5-140
AHI supine (h^{-1})	54	0-121.8
AHI non-supine (h^{-1})	38.2	3.2-141
T<90% (minutes)	231.5	0-523
ODI (h^{-1})	44.6	5.4-126
Median HR (bpm)	64.8	45.8-101.3

* n(%)
Abbreviations: AHI=apnea-hypopnea index; BMI=body mass index; bpm=beats per minute; HR=heart rate; Max=maximum; Min=minimum; ODI=oxygen desaturation index; T<90%= time with SpO_2 <90%.

No differences were found between the 2 operators (see Table 3). To identify variables associated with signal loss, all lost signals were correlated with age, body mass index (BMI), the supine and non-supine apnea-hypopnea indices, total recording time, and time spent in the supine and non-supine positions; however, no statistically-significant association was determined.

Small differences were observed in relation to gender in terms of the number of minutes of signal loss, as men lost more total signal than women at the expense of pulse oximetry; no gender differences were found for the other signals, and this disparity was not clinically-significant, in such a way, the probability of having to repeat studies in men generated an OR 1.66 (95% CI 0.4-6.88, p=0.47) in comparison with women. The complete comparison by gender is shown in Table 4.

Despite the need to repeat some PM there was a significant difference in costs as, according to our calculations, this PM format could represent a savings of as much as 75% with respect to a supervised PSG and 65% in relation to an PM performed in the hospital. Table 5 presents all cost calculations.

DISCUSSION

This study shows that PM performed at home with this format have good quality and are cost-effective, although patients moved through Mexico City with the monitor in place. This procedure made it possible to reduce data loss due to poor equipment handling by patients. Men lost more minutes of the pulse oximetry signal than women, but this difference was not clinically-relevant. No other variable analyzed was found to be associated with signal loss.

Table 2. Description of signal loss.

	Minutes		% TRT	
	Median	Min-Max	Median	Min-Max
Pulse oximetry loss (minutes)*	1.8	0-403.7	0.43	0-99
Respiratory flow loss (minutes)	0	0-238.6	0	0-61
Respiratory movement loss (minutes)	0	0-133.2	0	0-29
Total signal loss (minutes)	4.9	0-405	1	0-99

* Statistically-significant difference compared to all other signals.
Abbreviations: Max=maximum; Min=minimum; TRT=total recording time.

Table 3. Comparison of signal loss between operators.

	Operator 1 n=35	Operator 2 n=35	*p*
Pulse oximetry loss (minutes)	1.8 (0-384)	1.74 (0-403)	0.67
Respiratory flow loss (minutes)	0 (0-71.5)	0 (0-238.6)	0.38
Respiratory movement loss (minutes)	0 (0-133.2)	0 (0-110.7)	0.70
Total signal loss (minutes)	5.9 (0-384)	3.6 (0-405)	0.99
Total signal loss (%TRT)	1.6 (0-99)	0.7 (0-85)	0.87

Abbreviation: TRT=total recording time.
Variables summarized as medians (minimum-maximum)

Table 4. Comparison of signal loss by gender.

	Males	Females	*p*
Pulse oximetry loss (minutes)	3.1 (0-403.7)	0.78 (0-384)	0.02
Respiratory flow loss (minutes)	0 (0-238.6)	0 (0-71.5)	0.71
Respiratory movement loss (minutes)	0 (0-110.7)	0 (0-133.2)	0.95
Total signal loss (minutes)	7.9 (0-405)	1.4 (0-384)	0.00
Total signal loss (%TRT)	2 (0-85)	0.25 (0-99)	0.00

Abbreviations: TRT=total recording time.
Variables summarized as medians (minimum-maximum)

Table 5. Cost analysis expressed in US dollars.

	PSG	Hospital PM	Home PM
Use of equipment	34.87	4.47	5.36
Per-study Consumables	30.35	9.57	9.57
Use of Center`s installations	53.86	53.86	14.68
Technical cost of conducting study	71.81	71.81	4.50
Scoring cost	19.78	6.59	6.59
Additional cost for repeating the study	0	0	6.48
Insurance cost	0	0	2.37
Total	210.67	146.3	49.55

Abbreviations: PM=portable monitor, PSG=Polysomnography.

There are few studies of the amount of data loss that occurs when patients use a PM, as most information of this type has been generated with type 2 monitors (unsupervised PSG) thereby the SHHS (a multicenter study that analyzed over 6000 unsupervised at-home PSGs)[8] reported that 90% of recordings were of good quality, defined as at least 4 hours of interpretable recording; a definition that is less strict than the one applied in the present study.

A second difference was that in the SHHS study a qualified technician placed the sensors in the patient's home, a fact that could account for the differences found. In that study, the loss of cardiorespiratory signals (expressed as the % of total recording time) varied, but was generally higher than in our work. The loss of signals in the SHHS was as follows: loss of pulse oximetry, 6.8%; loss of respiratory flow, 21.3%; and loss of the thorax band, 21.3%. Obesity was associated with a decrease in the probability of success, but the factors of age, gender and AHI were not found to affect signal quality.

In a randomized study, Campbell and cols. compared signal quality between supervised PSG (type 1 monitor) and at-home PSG (type 2 monitor) in 30 OSAS patients. They found that 93.3% (28) of recordings were technically-acceptable (according to the SHHS definition).

Signal loss was greater at home than in the supervised studies and the signal lost most often at home was the effort band, while in the laboratory it was body position[11]. These findings contrast to our recordings, since we found no position failures. It is important to note, however, that different types of sensors were utilized. Campbell and cols. used individual sensors attached to the body, while in our study the position sensor was integrated into the monitor's recorder.

Golpe et al.[9] analyzed the quality of at-home PM using a type 3 monitor in a random sample of 28 patients who had the device installed at home by a qualified technician, and 27 who were trained to install and handle the device themselves. They found that 7% failed when the equipment was installed by a technician, *vs.* 33% when it was placed by the patient.

Unfortunately, that study did not describe signal loss. The only factors mentioned in relation to data loss were: patient failing to turn the equipment on, and/or poor quality or uninterpretable signals. Age, BMI and gender were not associated with recording quality. Interestingly, 81% of the recordings in our study were adequate and only 19% had to be repeated. Thus, compared to the data from Golpe et al., our recordings occupy an intermediate position between the 7% and 33% when the device was installed by a technician *vs.* the patient. Clearly, our PM format could reduce the percentage of data loss while reducing the need to mobilize a technician at night.

The only clinical variable associated with signal loss in our study was gender, as men lost more pulse oximetry signals than women. A possible explanation of this result could be the anatomical differences of the hand, since men tend to have more hair, deeper pigmentation and greater hand circumference; three variants caused by hormonal and genetic differences[12,13]. However, this finding did not constitute a clinical problem since male gender was not associated with an increased risk for repeating studies (OR = 1.66, p=0.47, 95% CI 0.4-6.88).

This study also reaffirms that PM is cheaper than PSG[14]. It is important to note that for our Center, performing PM with this technique represented a savings of 75% compared to supervised PSG, and of almost 65% with respect to PM conducted

in the hospital, even after considering the additional cost of insurance and the expense of repeat studies using a PSG as a second diagnostic test. The highest additional costs were for the salary of the personnel required to conduct studies and use of the installations; two factors that may show significant variation between institutions and countries.

Although cost-effective, the most important inconvenient of our portable monitoring technique would be technically inadequate, inconclusive or negative studies and the consequent need to repeat them, adding the possibility that the patient refuses a second monitoring, thus, it has been previously reported that the frequency of failure to a second sleep study can be up to 40%[10], however, this was not replicated in our patients and of the 13 repeated studies none refused to a second examination and its failure frequency was 0%.

Clinical practice guidelines and comparative studies have concluded that polysomnography is the most cost-effective diagnostic strategy for the diagnosis of moderate to severe OSAS in adults[10,15]; however, it is important to note that these studies and analyzes may not represent the real situation of an environment with limited resources such as ours where PSG is not available and the cost of not diagnosing and consequently not treating patients could be greater than the cost for repeating studies.

Limitations of this research include the fact that it is retrospective in nature, there was no prior selection of patients, most had severe OSA and that supervised PSG was not used as a reference standard for comparison, however, it is important to note that we did not set out to validate a previously certified monitor[16]. Also, while one specific model of monitor was used, the authors believe that this technique could be used with any PM that uses respiratory flow, respiratory movement and pulse oximetry as its main signals.

In Latin America, performing at-home PM increasingly constitutes the daily clinical work of a sleep unit, one advantage of this procedure is that the patient's natural sleep pattern can be monitored in her/his usual environment[17]. Also, this technique does not consume additional resources to those of a standard clinical service of the first or second level of care or even a preventive medicine unit; other advantages are that results are easily replicated, waiting times list could be reduced, no additional staff or travel through large cities is required, and the problem of limited resources is controlled. In sum, this approach could help resolve one of the greatest challenges that sleep medicine faces; namely, providing a mass strategy for diagnosing OSAS[18].

We can conclude that diagnosing OSAS by placing a portable monitor during the day, which the patient should turn on and off at home, is on average of good quality and is a cost-effective method.

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