Article published online: 2023-09-11

Nocturnal Polysomnography without Technical Supervision in the Diagnosis of Respiratory Sleep Disorders, Diagnostic Performance of Home and Sleep Laboratory Studies

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Sleep Sci 2023;16(3):e310–e316.

Abstract

Introduction Unattended Polysomnography (type 2 PSG) is a procedure for the diagnosis of sleep-disordered breathing (SDB). Published evidence on its performance and efficacy is limited. Available studies reveal a high rate of lost records that could limit its application.

Objective To assess the efficacy of type 2 PSG and the rate of studies that must be repeated due to critical loss of signals.

Methods prospective, descriptive study. Adult patients with suspected SDB were included. Unattended PSG was performed using portable equipment. 75 patients were connected at home and another 75 in the laboratory, without subsequent monitoring. Records were evaluated to determine the percentage of the night with adequate quality for each of the signals, considered as an evaluable signal for = 70% of the total recording time (TRT). The need to repeat the studies was also estimated. Results: 150 patients were recruited; 44% women; age 57.3 ± 15.4 years; BMI 29.4 ± 6.5. EEG and EOG signals were adequate in 149 records. Flow signal by pressure cannula was adequate in 146 and by thermistor in 67.8%. In only one study the signal of both effort bands were inadequate. Oximetry was lost in 4 cases. Ten tracings (6%) met the criteria for repetition; 8 hospital and 2 home.

Conclusions Acceptable records were obtained in most unattended PSG studies, both at home and in the sleep laboratory. The rate of repetition of studies due to loss of signal was 6%, with failure in SaO2 or in flow signals being the main cause of the indication.

Keywords
- sleep apnea
- obstructive
- polysomnography
- monitoring
- ambulatory
- home care services
- hospital based

received
July 27, 2022
accepted
December 13, 2022

DOI https://doi.org/10.1055/s-0043-1772809.
ISSN 1984-0659.

Thieme Revinter Publicações Ltda., Rua do Matoso 170, Rio de Janeiro, RJ, CEP 20270-135, Brazil

Introduction

The gold standard method for diagnosing sleep-disordered breathing (SDB) is Nocturnal Polysomnography (PSG) performed in a sleep laboratory under continuous technical supervision. While it is accurate with a low signal failure rate, it is also expensive and requires continuously available qualified human resources.[1,2]

The high prevalence of SDB, and the growing alertness of the population have increased the demand for diagnostic studies and, consequently, the waiting list for tests.[2–8] In this context, simplified diagnostic modalities have emerged, using portable equipment outside the sleep laboratory.[8,9]

The unattended PSG or type 2 PSG (PSG-2) includes the same signals as conventional PSG, but without nocturnal technical supervision. This technique can be performed in the sleep laboratory, general hospital ward, as well as at patient's home, and although it saves human resources cost, at the same time eliminates the possibility of intervention during the study to correct potential signal failures.[2]

There is insufficient evidence to determine the diagnostic utility of PSG-2, especially regarding the rate of signal loss and the need to repeat the studies, which varies between 5 and 20% according to different authors.[8–11]

Some clinical guidelines for obstructive sleep apnea (OSA) recognize PSG-2 as a valid diagnostic method in patients with suspected OSA.[12] The AASM recommends evaluating patients with suspected OSA using both PSG-1 and the Home Sleep Apnea Test (HSAT), defined as PSG-2 or respiratory polygraphy, but points out its disadvantages compared to PSG-1 in terms of fewer parameters registered and possible technical failures due to lack of monitoring.[2]

New and sophisticated portable equipment, smaller in size and with high signal quality, would make it possible to optimize and increase the performance of this technique with potential operational advantages. In any case, it is necessary to determine its diagnostic efficacy and identify the main flaws in the signals obtained when performing PSG-2 studies.[13,14]

The objective of this study was to assess the efficacy of type 2 PSG using a portable polysomnograph, both at home and in the sleep laboratory, and the rate of studies that must be repeated due to critical loss of signals.

Material and Methods

Study Design

Descriptive and prospective study, conducted in two sleep centers in the City of Buenos Aires, the Hospital de Clinicas José de San Martín (HCJSM) of the University of Buenos Aires and the Argentine Institute of Neurological Research (IADIN), among the months of October 2017 and March 2018. An independent ethics committee previously approved the study. All study procedures were performed in accordance with the ethical standards described in the 1964 Declaration of Helsinki and its subsequent addenda and modifications. The patients had to sign an informed consent to participate in the study and the confidentiality of the data was guaranteed.

Sample

Consecutive adult patients ($\geq$ 18 years) of both sexes with suspected OSA who gave their consent to participate in the study were recruited.

Patients with clinical manifestations and history consistent with congestive heart failure, severe chronic obstructive pulmonary disease, respiratory failure from other causes, neuromuscular diseases, and psychiatric or cognitive disorders that could interfere with the study processes were excluded. Likewise, studies lasting less than 6 hours were also excluded.

OSA Diagnosis

Sleep studies were performed with two Alice-PDX polysomnograph (Philips-Respironics, USA). These portable devices allow, depending on the configuration chosen, to conduct both PSG and Respiratory Polygraphy (level 3 studies), under technical supervision or even without supervision. They can record flow through a nasal pressure cannula (Flow-P) and an oral thermistor (Flow-T); respiratory effort by inductance plethysmography (RIP); SaO2; heart rate and body position. An additional module incorporates EEG, EOG, CHIN and EMG. The recorded signals are downloaded to a PC and analyzed with the corresponding software (Sleepware G3 version 3.2.1; Respironics, USA). The equipment has a display that indicates the recording quality of each connected sensor, which allows verifying that the installation is correct.

PSG-2 studies were performed using the following configuration: Flow-P; Flow-T; RIP bands of chest (RIP-T) and abdomen (RIP-A); body position; vibratory snoring; SaO2; heart rate; ECG; 2 EEG channels (C3-M2 and O2-M1); 2 EOG and EMG and CHIN channels.

The recordings were made during the patient's usual sleeping hours and a minimum recording time limit of 6 hours was established.

Two trained technicians, with more than 5 years of experience in polysomnographic studies, were responsible for connecting the equipment on the night of the study. One of them dealt with the patients studied in the Sleep Laboratory and the other with the patients evaluated at home. After placing the sensors, the equipment was turned on and it was verified that the recording quality was adequate according to the light indicator on the display, then the recording began, and the technician left the room.

The patients studied in the Sleep Laboratory slept in one of the rooms, without any connection to monitoring systems, both tracing and video. Although the technician remained in the sleep laboratory throughout the night, he did not enter the room until the end of the study after 6 hours, except to respond to a call from the patient.

The installation of the devices in the home studies was also conducted by a technician who assisted at night, according to the usual sleep schedule of each patient. He connected the sensors, verified the recording quality, started the recording, and left the home, returning the next morning to pick up the equipment. The patients were instructed on how to manage the equipment in case of disconnection or

the need to get up at night to go to the bathroom and how to turn it off and disconnect the next morning. In addition, they were instructed to stay in bed with the equipment on for at least 6 hours.

Patients were encouraged to get up early on the day of the study, not to nap, not to take stimulating substances after noon (coffee, tea, other caffeinated beverages), not to engage in vigorous physical activity after 5:00 PM and that they take the medication that they usually consume daily.

Study Procedures

Age, sex, weight, and height were recorded and the body mass index (BMI) of each subject was calculated. The patients evaluated at the HCJSM were scheduled to perform the study in the sleep laboratory, while the patients recruited at IADIN underwent PSG-2 at home.

All records were manually scored by an expert physician at each center, using standardized criteria and according to guidelines established by the AASM.[15] Tracings were analyzed at epochs of 30 seconds for neurological signals and 2 minutes for respiratory signals.

Apnea was defined as any reduction in airflow greater than 90% and hypopnea if the reduction ranged between 30% and 90% associated with a drop in saturation of >3% and/or a microarousal reaction in the EEG, in both cases for a time greater than 10 seconds. The presence or absence of respiratory effort during apnea defined its obstructive or central origin. The software calculates the apnea-hypopnea index (AHI), which represents the number of respiratory events (apneas and/or hypopneas) per hour of sleep. A pathological AHI was considered when it was ≥ 5/h and the following severity categories were established; mild (AHI between 5 and 14.9/h), moderate (AHI between 15 and 29.9/h) and severe (AHI ≥ 30/h).[15]

The following polysomnographic indices were also obtained from each study:

- Total recording time (TRT): Time elapsed from the start to the end of the recording, expressed in minutes.
- Total sleep time (TST): it is the recorded time in minutes with electrical sleep activity in EEG.
- Sleep onset latency (SL): is the time in minutes that elapses from the start of the recording until the patient presents his first stage of sleep. Considered normal between 5 and 30 minutes.
- Sleep efficiency (SE): ratio between recording time and sleep time, normal ≥85%.
- REM sleep percentage: measure of the density of REM sleep, relative to total sleep time, expressed as a percentage. Normal between 20 and 25%.
- T90%: total time expressed in minutes that the patient spends saturating below 90% throughout the night.

The quality variables monitored were the following: EEG, EOG, CHIN, EMG, Flow-P, Flow-T, RIP-T, RIP-A and SaO2.

For each recorded channel, the percentage of time in which the signal had adequate quality to allow the interpretation of physiological and pathological data was calculated. Based on this, the following signal quality categories were established for each channel:

- Category 1: "Optimal signal": good quality tracking ≥90% of TRT.
- Category 2: "Adequate signal": good quality tracking ≥70% of TRT.
- Category 3: "Inadequate signal": good quality tracking <70% of TRT.

Criteria for major failure of the study and indication for its repetition were the presence of one or more of the following situations:

- Signal loss of both flow channels ≥30% of TRT.
- Signal loss of both effort band channels (RIP-T; RIP-A) ≥30% of the TRT.
- SaO2 signal loss ≥30% of the TRT.
- Signal loss of both EEG channels ≥30% of the TRT.

Statistical Analysis

The normality of the distribution of continuous data was evaluated by histograms, kurtosis, skewness, and Schapiro Wilks test. Means and standard deviations were used to present normally distributed data, and medians and interquartile distance (ID) for non-normally distributed data. Categorical data will be presented by frequencies and percentages.[16]

In the univariate analysis, the Chi^2 test and Fisher's exact test were used for categorical variables; Wilcoxon's t-test or rank sum for continuous variables according to data distribution. To make the comparison considering the variable of repetition of the study, a sample of controls was selected according to sex and age. Values of $p < 0.05$ were considered significant. Data were analyzed using SPSS 15.0 (SPSS Inc., Chicago, USA).[16]

Results

The study sample included 150 patients, seventy-five studied at home and another seventy-five in the sleep laboratory. ►**Table 1** summarizes the characteristics of the population and the results of the polysomnographic variables, both for the general population and for the subpopulation of patients studied at home and in the sleep laboratory.

Patients studied at home were younger and had higher TRT, TST, and percentage of REM sleep, longer sleep latency, and lower AHI than hospital patients. Sleep efficiency was reduced in both groups. (►**Table 1**).

The analysis of the quality of the records is presented in ►**Table 2**. The EEG and EOG signal were adequate in 149/150 patients. In all studies, at least one EMG channel suitable for interpretation was obtained. In 75.3% of the studies, the CHIN signal was optimal, although in 35/37 of the records classified as inadequate signal, CHIN was not recorded due to an error in the configuration of the device, which should not be strictly considered a loss of the signal during the study.

Regarding the flow channels, the signal from the nasal pressure cannula was adequate in 97% of the cases and that of

Table 1 Sociodemographic and polysomnographic variables

Variable	In-Lab PSG-2 (n = 75)	Home PSG-2 (n = 75)	P value
Males, n (%)	45 (60%)	39 (52%)	0.324
Age, years*	62 (19)	55 (22)	0,023
BMI, kg/m^{2}*	28.66 (8)	27.34 (9)	0.416
TRT, minutes*	373.2 (23.4)	427 (42.75)	<0.001
TST, minutes*	320 (83)	343.5 (54.5)	0.003
SE, %*	83 (20.3)	82.5 (11.25)	0.442
SL, minutes*	7 (18)	28.5 (28.7)	<0.001
%REM*	8 (10)	16 (8.25)	<0.001
AHI, ev/h*	25.1 (29.2)	7.9 (13.4)	<0.001
T90, minutes*	8.6 (35.6)	3.55 (42)	0.833

*Values expressed as mean (SD). BMI: body mass index; TRT: total recording time; TST: total sleep time; SE: sleep efficiency; SL: sleep latency; %REM: % of time spend on REM sleep; AHI: apnea hypopnea index; T90: time in minutes with SaO2 under 90%.

the oral thermistor in 53%. In the subgroup of hospitalized patients, the oral thermistor signal was not recorded in 32 patients due to sensor breakage and delays in its replacement. It should be noted that, in fact, these cases would not strictly constitute an intra-study signal failure. For the effort bands (RIP-T; RIP-A) and SaO2, satisfactory records were obtained in 96% of the cases. (►**Table 2**)

When comparing the studies carried out in the laboratory versus at home, no significant differences were found in the percentages of adequate recordings for most of the signals, except for EMG. However, since two EMG channels were recorded, at least one adequate EMG signal could be obtained in all patients. Regarding the CHIN and oral thermistor signals, as mentioned above, activity could not be recorded in a significant subgroup of patients due to sensor malfunction, not due to loss of signal during the study, so it would not be correct to attribute these cases to factors inherent to the type of PSG. If these cases are excluded, no differences are found in terms of loss of these signals between laboratory and home studies (CHIN: 2/75 vs. 0/40, p = 0.248; Flow-T: 16/43 vs. 22/75, p = 0.616) (►**Table 3**)

Table 2 Quality variables in the total population

	Total Population (N = 150)		
Signal	Optimal	Adequate	Inadequate
EEG1	98.7	99.3	0.7
EEG2	97.3	97.3	1.3
EOG1	98.7	99.3	0.7
EOG2	98.7	99.3	0.7
CHIN	73.3	75.3	24.7
EMG1	73.3	88.7	11.3
EMG2	97.3	100	0
Flow-P	92.6	97.3	2.7
Flow-T	6.6	53.3	47.7
RIP-T	88.6	96.7	3.3
RIP-A	94	96.7	3.3
SaO2	92.6	96	4

Values expressed as % of the total. EEG: Electroencephalography; EOG: Electrooculography; CHIN: chin electromyography; EMG: leg electromyography; Flow-P: nasal pressure cannula flow sensor; Flow-T: thermistor sensor; RIP-T: thoracic respiratory inductance plethysmography; RIP-A: abdominal respiratory inductance plethysmography; SaO2: arterial oxygen saturation.

Table 3 Adequate signal for each channel and indication of repeat studies for each subgroup

Signal	Laboratory (N = 75)	Home (N = 75)	P value
EEG1	74 (98.6)	75 (100)	0.363
EEG2	73 (97.3)	75 (100)	0.128
EOG1	74 (98.6)	75 (100)	0.363
EOG2	74 (98.6)	75 (100)	0.363
CHIN	73 (97.3)	40 (53.3)*	<0.001
EMG1	75 (100)	58 (77.3%)	<0.001
EMG2	75 (100)	75 (100)	0.620
Flujo-P	73 (97.3)	73 (97.3)	0.928
Flujo-T	27 (36.0)**	53 (70.7)	<0.001
RIP-T	70 (93.3)	75 (100)	0.075
RIP-A	70 (93.3)	75 (100)	0.075
SaO2	71 (94.6)	73 (97.3)	0.628
Repeat indication	8 (10.7)	2 (2.7)	0.05

Values expressed as n (%) of the total. *Chin tracings were registered in only 40 home studies, all of them with an adequate signal. ** Flow thermistor signal was registered in only 42 in-Laboratory patients. EEG: Electroencephalography; EOG: Electrooculography; CHIN: chin electromyography; EMG: leg electromyography; Flow-P: nasal pressure cannula flow sensor; Flow-T: thermistor sensor; RIP-T: thoracic respiratory inductance plethysmography; RIP-A: abdominal respiratory inductance plethysmography; SaO2: arterial oxygen saturation.

We found that ten of the 150 patients (6.7%) met the criteria to repeat the study, eight had been studied in the hospital. The main indication of repetition was the failure of the SaO2, followed by the loss of both flow channels. In one study, what forced us to repeat it was the failure of the RIP and in another the EEG. (►**Table 4**)

When comparing the population with repetition criteria against the rest of the patients, in a 1:4 ratio, no significant differences were detected. (►**Table 5**).

Discussion

The most relevant finding of our research was that the defined criteria for repeat PSG-2 were present in 6.7% of cases, this value is lower than those previously reported. Portier in 2000, in a sample of 103 patients, compared in-lab PSG-1 with PSG-2 performed at home, obtaining repetition rates of 5% and 20%, respectively, mainly due to loss of the flow signal. They attributed the difference to the fact that

Table 4 Studies with repetition criteria: causes

Variables	Total (N = 150)	Laboratory (N = 75)	Home (N = 75)
PSG test with repetition criteria	10 (6.7%)	8 (10.6%)	2 (2.7%)
Loss of both flow channels >30% ot the night	4	2	2*
Loss of both effort bands >30% of the night	1	1	0
Loss of SaO2 >30% of the night	6	4	2*
Loss of both EEG channels >30% of the night	1	1	0

EEG: electroencephalography; PSG: polysomnograph; SaO2: arterial oxygen saturation.
*The 2 studies with signal loss in both flow channels correspond to the same patients with oximetry failures.

Table 5 Comparison between patients with and without indication to repeat PSG-2

Variables	Patients with indication to repeat study (N = 10)	Patients without indication to repeat study (N = 39)¥	P value
BMI	27,4 (7)*	30 (10)*	0.778
In-lab study	8 (80%) #	22 (56.4%) #	0.316
TRT	367 (36)*	392 (53)*	0.332
TST	306 (103)*	339 (58)*	0.396
AHI	59 (57)*	15 (33)*	0.256
T90	9 (54)*	6 (41)*	0.890

¥ controls selected by age and sex; *values expressed as mean (SD); # values expressed as n (%). BMI: body mass index; TRT: total record time; TST: total sleep time, AHI: apnea hypopnea index; T90: time in minutes with SaO2 under 90%.

patients had to insert the nasal thermistor by themselves, without technical assistance.[7] Kapur evaluated a cohort of 6,802 patients from the Sleep Heart Health Study (SHHS) for PSG-2 failure rate and signal loss and attempted to correlate these results with population characteristics (age, gender, obesity, and SDB). One in ten patients required re-study, although the relationship with the characteristics was weak.[10] However, these studies used less strict quality criteria than those adopted by us. Portier considered as failure criteria a loss of more than 80% of the night in the flow signal, impossible sleep staging and records of less than 180 minutes.[7] In the cohort analyzed by Kapur et al, the visual evaluation of the signals was done at half-hour intervals and their repetition criteria were broader: 4h with loss of SaO2, or flow signal, or respiratory effort (abdominal or thoracic).[10] In our study, we have analyzed all the signals individually, even for the case of parameters that can be displayed in more than one channel, qualifying as inadequate signal all those that had more than 30% of non-analyzable trace. Furthermore, our failure criteria were more stringent, as ≥30% loss of signal from both flow channels, both stress channels, oximetry, or EEG signal were taken individually as indicators to repeat the PSG.

Iber et al studied seventy-two patients who underwent PSG-2 at home and PSG-1 in the laboratory, with an overall failure rate that was also higher than ours (15.7%), with no differences between home and laboratory. They found higher TST and sleep efficiency at home, with similar AHI values.[17]

Campbell studied thirty patients who underwent PSG-2 at home and PSG-1 and PSG-2 in the laboratory on three different nights. They found a 93% of clinically acceptable home studies, against 100% of in-lab studies, due to a greater signal loss at home, but still determined that channel redundancy mitigates signal loss, and that the method is useful.[18]

In another study, the results of PSG-1 in the laboratory were compared with PSG-2 at home in sixty-six patients, obtaining 4.7% of poor-quality studies at home versus 1.5% in the laboratory.[11] Subsequently, the same group studied a sample of ninety-five patients who underwent two PSG-2 tests at home, comparing the placement of sensors at home versus in the laboratory. Ninety-three percent of the studies were successful, with a similar failure rate for both the home and sleep lab settings ($p = 0.33$). Home placement was widely preferred by patients.[19]

Our sample size exceeded that of most published studies and includes patients studied with PSG-2 both at home and in the laboratory. We found no significant differences in sleep efficiency related to the study site and, in fact, it was decreased in both. However, sleep latency was higher in home patients. This could be attributed to the inconvenience of the method itself and the concern that conducting a study at home without the presence of a supervising technician could eventually generate. On the other hand, the patients studied at home had a significantly lower AHI (7.9/h vs. 25.1/h), which could also have affected sleep architecture (higher density of REM sleep). We attribute this difference to the fact that they are different populations with clearly more compromised hospital patients.

In our study, the greatest indication of repetitions was due to failures in the oximetry signal, followed by failure in the

flow signal. These results are similar to those shown by previous studies.[7,9,20] In this regard, Mykytyn, raises the need to improve the methods of fixing sensors or to incorporate alarms that indicate the absence of SaO2 signal to reduce the error rate.[9]

When analyzing the respiratory flow signals, 97.3% of acceptable tracings were observed for the nasal pressure cannula channel and 53.3% for the oral thermistor channel. Although the thermistor used in the sleep laboratory equipment failed to record this signal in thirty-two studies, oral thermistor flow is often technically difficult to obtain, as it is only recorded if the patient breathes through the mouth. In addition, due to its location, it is more likely to be annoying and that the patient removes it while sleeping. The possibility of recording the ventilatory flow by more than one method in the same study guarantees that the trace can be analyzed despite the failure of a channel. In this sense, other studies previously published in the literature also point out the importance of channel redundancy.[18,20] The effort band signal was acceptable in more than 96% of cases.

Comparing each of the signals separately, significant differences between home and laboratory were only found in one of the EMG channels. However, unlike what has been published by other authors, a higher rate of study repetition criteria was observed at the hospital level (p 0.05).[7,11,18] In this sense, the publications that compare PSG-2 at home versus PSG-1 in the laboratory attribute the greater loss of signal at home to the lack of technical supervision capable of quickly correcting the eventual sensor failure. There are no studies comparing at home versus in-lab PSG-2 in different populations as we do in our work. When trying to analyze the factors that could explain these differences, we must point out that the patients studied at home were younger, and therefore, we could speculate that they possibly had a greater capacity to deal with technology than older patients. On the other hand, two different technicians were specifically assigned to each population. Although both are trained and qualified personnel, the individual differences inherent in the technique are inevitable and this could have influenced the patient's learning and adherence to the study. Finally, when analyzing the ten patients in whom the PSG-2 failed versus the patients whose study was acceptable, there were no differences in age, gender, or BMI.

This study has some limitations. It was conducted in two different populations, one corresponding to a reference hospital center, which receives referrals from other centers, and a private center. Populations were not randomly assigned to both methods. This could be considered a weakness when evaluating the place of study as a factor that influences the quality of the records. As noted above, two different technicians were assigned to each population, potentially leading to technical differences in sensor placement and patient instruction to proceed with the unsupervised study.

As another limitation, modern technology was used in this study, which allows PSG-2 traces to be obtained with a portable device, without connections to a PC or notebook, which simplifies its installation and use at night, so these data could not be extrapolated to patients studied with a different technology.

On the other hand, the study has the following strengths. The sample size exceeds that of most published studies, with stricter and better-defined repeatability criteria. In turn, modern technology was used, with equipment specially designed for recording unsupervised PSG, and it is the first time that PSG-2 has been compared in the laboratory versus at home in different populations.

Conclusion

The PSG-2 offers an effective option for the study of patients with suspected OSAS. The results obtained in this work show a high rate of diagnostic yield and a low repetition rate. The PSG-2 constitutes an alternative to shorten waiting list for sleep studies and potentially reduce costs.

Conflict of Interest
None declared.

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