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An Alternative In-Home Protocol to Diagnose and Treat Obstructive Sleep Apnea

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Abstract

Objective Obstructive sleep apnea (OSA) is a major public health problem of pandemic proportions. In-laboratory OSA diagnosis and continuous positive airway pressure (CPAP) titration are insufficient, considering the number of patients affected. Finding alternative ways to diagnose and treat OSA is mandatory, especially in this era of the coronavirus disease 2019 (COVID-19) pandemic. The present study aims to describe an alternative in-home protocol to diagnose and treat OSA.

Materials and Methods We enrolled consecutive patients aged ≥ 18 years with moderate/severe OSA, who underwent in-home type-III polysomnography and home-based titration with automatic CPAP, coupled with an oximetry sensor for 3 consecutive nights. Patients were remotely monitored for 90 days to evaluate CPAP compliance and the use of an engagement tool was encouraged.

Results We included 86 participants. The median time until the diagnosis was of one day. The mean time from the baseline visit until the acquisition and initiation of the CPAP therapy was of 33 (range: 17 to 52) days. Telemonitoring ensured good compliance in the first 30 (79.2%), 60 (76.3%) and 90 (74.3%) days, with an average daily use of 6.2 ± 1.4 h, 6.0 ± 1.4 h, and 6.0 ± 1.3 h respectively. About 1/3 of the patients used the engagement tool, and CPAP compliance was significantly higher among these patients compared with those who did not used the tool: 89.9% versus 73.5% ($p < 0.002$), 87.9% versus 70% ($p < 0.003$), and 86.6% versus 67.6% ($p < 0.001$) at 30, 60, and 90 days respectively.

Conclusion We demonstrated that an alternative in-home protocol to diagnose and treat OSA is effective, ensuring good CPAP compliance after 90 days. Telemonitoring and engagement tools could be strategies to improve CPAP compliance.

Keywords

- obstructive sleep apnea
- diagnosis
- continuous positive airway pressure
- compliance
- telemonitoring

Introduction

Obstructive sleep apnea (OSA) is characterized by recurrent episodes of partial or total airway obstruction during sleep,[1] commonly associated with snoring, sleep fragmentation, intermittent hypoxia, daytime sleepiness, and cognitive impairment.[2] The condition is highly prevalent in the adult population, with recent estimates suggesting that the number of people with OSA worldwide is of up to 1 billion.[3]

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Underdiagnosis places a substantial burden on patients and health care systems, as OSA could be associated with many diseases, including hypertension, type-2 diabetes, heart failure, atrial fibrillation, and stroke.[4,5] Type-I polysomnography (PSG) is the gold standard for OSA diagnosis, but it must be performed in a sleep laboratory during an entire night with an experienced technician.[6] The growing demand for sleep studies and the limitation of sleep beds and laboratories result in long waiting periods for the exam. In-home portable PSG (type-III) has been increasingly used as an alternative due to its simplicity and cost-effectiveness, and it has also been shown to be effective in the diagnosis of OSA.[7]

Continuous positive airways pressure (CPAP) is the first-line treatment for patients with moderate and severe OSA,[8] improving daytime sleepiness, quality of life and cognition. Traditionally, in-laboratory CPAP titration is performed to evaluate the patient's preference and CPAP parameters. Auto-CPAP with telemonitoring emerged as one alternative to simplify CPAP prescription and increase adherence.[9] Home titration of CPAP with telemonitoring has proven to be very useful, especially in times of a pandemic, saving time and resources and facilitating patient access to OSA therapy.[10]

The present study aims to evaluate an alternative in-home protocol to diagnose and treat OSA, to ensure good CPAP compliance. We hypothesize that this new approach to diagnosis and treatment may be as effective as the classic sleep laboratory model.

Materials and Methods

The present study was conducted in a private clinic in the city of Recife, state of Pernambuco, Brazil. From September 2020 to April 2022, consecutive patients aged ≥ 18 years and diagnosed with moderate and severe OSA were invited to participate. To standardize the follow-up with telemonitoring, participants were instructed to buy **Air**Sense 10 (ResMed® Corp., San Diego, CA, USA) machines and nasal pillows or nasal masks were provided. Patients with comorbidities such as heart failure or predominant central sleep apnea and those on previous CPAP use were excluded, as well as those who chose a CPAP device from another manufacturer. The study was approved by the Ethics in Research Committee of the Hospital Universitário Oswaldo Cruz/Pronto Socorro Cardiológico Universitário de Pernambuco (HUOC/PROCAPE) Hospital Complex under protocol number 4.237.460. All patients who agreed to participate signed an informed consent form.

Home Diagnosis

All patients performed type-III PSG (ApneaLink, ResMed Healthcare Professional) with the following channels: heart rate, airflow, thoracic movement, and oximetry. Apnea was defined as complete cessation of airflow for more than 10 seconds; it can be central or obstructive based on the absence or presence of respiratory effort respectively. Hypopnea was defined by a reduction in oronasal flow $\geq 30\%$ for more than 10 seconds, followed by a fall in oxygen saturation (SpO_2) $\geq 3\%$. The apnea-hypopnea index (AHI) was calculated by adding the total number of respiratory events (apneas + hypopneas) divided by the recording time of the device. Exams with a record of at least 4 hours were considered valid and patients were classified as having no OSA (AHI < 5), mild OSA (AHI ranging from 5 to 14.9), moderate OSA (AHI ranging from 15 to 29.9), and severe OSA (AHI ≥ 30).[11]

Home-based Automated CPAP Titration

The CPAP was set in automatic mode, preferentially with nasal pillows or nasal masks, and an oximeter was coupled to the device for the duration of the titration. Heated humidification was offered just in case of nasal discomfort after beginning the CPAP therapy. Patients were submitted to daily remote evaluations by a respiratory physiotherapist using the cloud-based AirView (ResMed Healthcare Professional) telemonitoring system. The physiotherapist was able to remotely make adjustments to the CPAP prescription when necessary. All patients started titration with CPAP in automatic mode with pressures that were adjusted from 4 cmH2O to 12 cmH_2O.

The titrated pressures were acquired from the 95th percentile pressure obtained through the 3-day equipment monitoring data.

OSA Treatment

The use of fixed pressures was suggested to patients who required CPAP pressures below 10 cmH_2O during the titration period. The minimum pressure used was of 6 cmH_2O for patients who used fixed pressure as treatment. For patients requiring higher pressures and for those who preferred automatic devices, the maximum pressure was set up to 2 cmH_2O above the 95th percentile pressure. Patients were registered in the AirView system and submitted to daily remote monitoring for 90 days in order to assess compliance to the treatment. Good CPAP adherence was considered as the use of the device for ≥ 4 h for $\geq 70\%$ of nights in the first 90 days.[9] In addition, all patients were instructed and encouraged to use an engagement tool via mobile application (myAir, ResMed Healthcare Professional).

Statistical Analysis

Normality of distribution was evaluated using the Kolmogorov-Smirnov test, with the results expressed as mean $\pm$ standard deviation (SD) values, medians (interquartile range, IQR) or percentages as appropriate. The Pearson Chi-squared test was used in the comparisons among proportions, and the Mann-Whitney U test for independent samples was used to compare variables. The Kruskal-Wallis and analysis of variance (ANOVA) tests were used to compare variables among groups when appropriate. Values of $p < 0.05$ were considered statistically significant.

Results

Initially, 110 patients were screened and 24 were excluded, resulting in 86 patients included in the final analysis (►**Fig. 1**). The patients were predominantly middle-aged

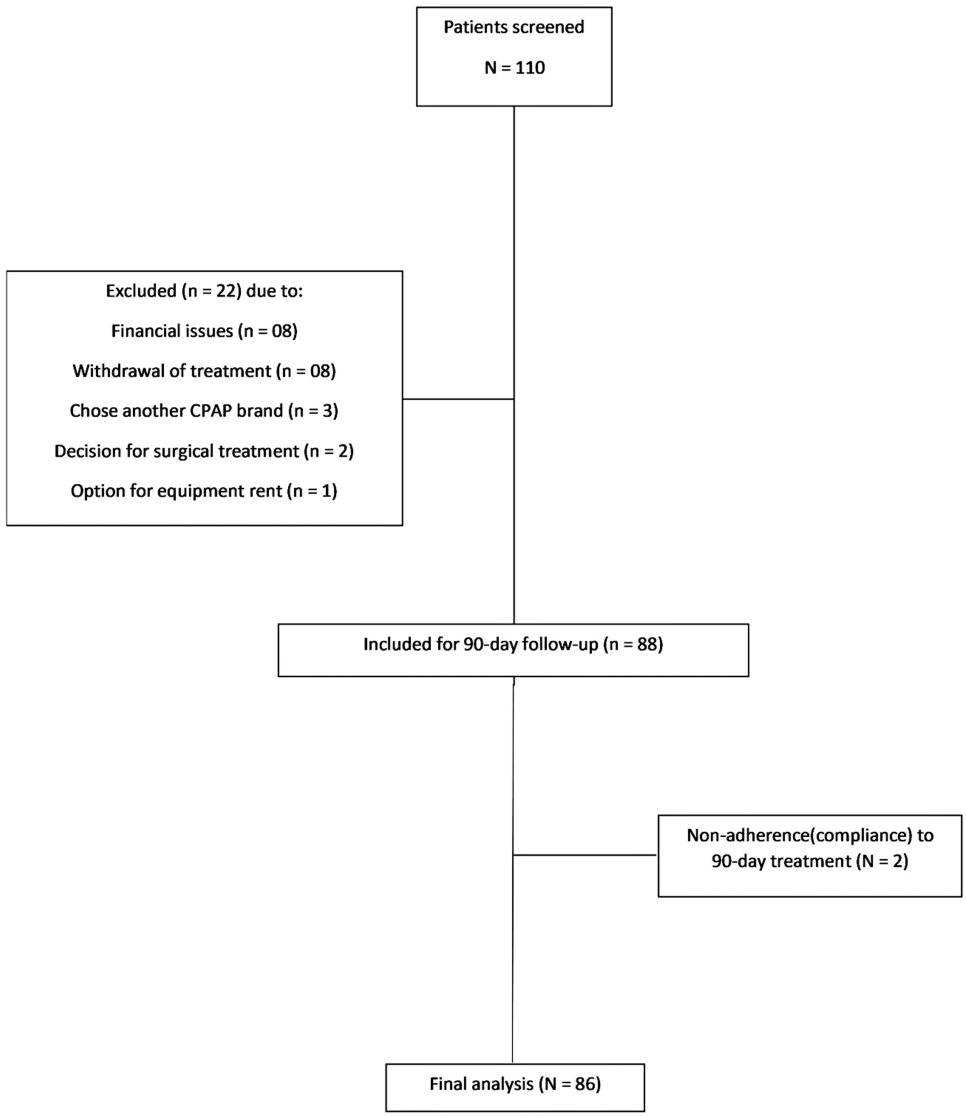

Fig. 1 Flowchart of patient recruitment.

obese men, with long neck and waist circumferences (►**Table 1**) and severe OSA (►**Table 2**).

The median time to diagnosis was of only one day. Likewise, home titration proved to be effective in controlling OSA, as demonstrated by the low AHI (< 5 events/h) and satisfactory SpO_2 (> 90%) reported (►**Table 2**). After home titration and CPAP prescription, the patients took approximately 7 (range: 4 to 21) days to purchase the CPAP device and begin therapy. The mean total time from the first physician visit to the beginning of the CPAP therapy was of 33 (range: 17 to 51) days. We adopted a fixed pressure after the initial CPAP titration in 56% of the cases, and the mean CPAP pressure was of $10cmH_2O$ (►**Table 2**).

Good compliance to the therapy was observed in the first 30 (79.2%), 60 (76.3%), and 90 (74.3%) days, with an average daily use of 6.2 ± 1.4 h, 6.0 ± 1.4 h, and 6.0 ± 1.3 h respectively (►**Table 3**). The proportion of patients who registered and used the engagement tool was of 34.9%. Compliance to the CPAP therapy was significantly higher in patients who used the MyAir engagement tool compared with patients who did not used it: 89.9% versus 73.5% ($p < 0.002$) at 30 days, 87.9% versus 70% ($p < 0.003$) at 60 days, and 86.6% versus 67.6% ($p < 0.001$) at 90 days respectively (►**Fig. 2**) It is worthy of note that, on average, the patients who used this tool were younger than those who did not (age: 45 ± 11 years versus 57 ± 14 years respectively), and the vast majority were men (n = 26; 86.6%; $p < 0.01$).

Discussion

The present study evaluated the feasibility of in-home diagnosis and treatment of OSA and reported interesting findings. First, in-home diagnosis enabled us to keep the time between diagnosis and treatment initiation short. Second, the daily telemonitoring ensured a good compliance in the first 90 days of treatment. Third, self-monitoring via a mobile app improved patient engagement with the treatment and ensured better compliance.

Table 1 Anthropometric and clinical characteristics of patients with moderate/severe OSA.

Variable	N = 86
Age (years)	53.4 ± 14.6
Male gender: n (%)	60 (69.8)
Body mass index (kg/m^2)	30.6 (27.6–34.5)
Neck circumference (cm)	40 (38–43)
Waist circumference (cm)	107 (101–120)
Heart rate (bpm)	78 ± 11
SpO_2 (%)	97 (96–97)
Office systolic BP (mmHg)	130 (120–141)
Office diastolic BP (mmHg)	75 (69–83)
Hypertension: n (%)	56 (65.1)
Diabetes: n (%)	17 (19.8)
Dyslipidemia: n (%)	22 (25.6)
COVID-19: n (%)	31 (36)
Nocturia: n (%)	42 (48.8)
Smoker: n (%)	2 (2.3)
Physical activity: n (%)	41 (47.7)
Use of antihypertensive: n (%)	56 (65.1)
Regular use of sleeping medication: n (%)	9 (10.5)
ESS score	9 ± 5

Abbreviations: BP, blood pressure; COVID-19, coronavirus disease 2019; ESS, Epworth Sleepiness Scale; OSA, obstructive sleep apnea; SpO2, peripheral oxygen saturation.
Note: Data are presented as median (interquartile range, IQR) values, mean ± standard deviation values, or as n (%).

Table 2 Characteristics of the sleep study and titration with automatic device.

Variable	N = 86
Portable polysomnography	
AHI (events/h)	39 (29–55)
Baseline SpO_2 (%)	95 (94–96)
Mean SpO_2 (%)	93 (91–94)
Minimum SpO_2 (%)	79 (72–82)
ODI	35 (27–49)
SpO_2 time <90% (%)	17 (6–41)
Titration with automatic device	
95th percentile (P95)	10 (9.2–11)
SpO_2 (P95)	96 (95–97)
AHI (events/h)	2 (1–3)
Leak (L/min)	23. ± 12.9
Treatment compliance (h/night)	6.7 ± 1.4

Abbreviations: AHI, apnea-hypopnea index; ODI, oxyhemoglobin desaturation index; SpO_2, peripheral oxygen saturation.
Note: Data are presented as median (interquartile range, IQR) or mean ± standard deviation values.

Nearly 1 billion adults aged 30 to 69 years worldwide are estimated to be affected by OSA, with almost 425 million of them presenting moderate to severe OSA and requiring treatment.[3] Despite all efforts to diagnose and treat OSA patients, available data suggest that most cases remain undiagnosed and, therefore, untreated.[12] The significant impact of OSA on the patient's health, notably due to the associated comorbidities and decrease in quality of life, is associated with a high economic and societal burden.[13]

Polysomnography remains the gold standard for the diagnosis;[14] however, the need for hospitalization and use of a sleep bed to perform this evaluation makes the exam expensive, complex, and uncomfortable for the patient.[15] Easier, large-scale, and more cost-effective diagnostic methods are needed, especially in the era of the coronavirus disease 2019 (COVID-19) pandemic. In the present study, the use of portable monitors enabled us to establish the diagnosis within 2 days from the medical consultation, while ensuring safety and convenience to the patients.

Auto-CPAP titration test with coupled oximetry demonstrated that only 3 nights were necessary to evaluate the adequate 95th percentile needed to treat OSA and correct the resulting hypoxemia. Kuna et al.[16] showed that a home-based strategy for OSA diagnosis and therapy was non-inferior to a traditional in-laboratory PSG in terms of acceptance and treatment compliance. Moreover, Berry and Sriram,[17] found no difference regarding AHI and CPAP compliance between patients who underwent automatic CPAP compared with in-laboratory CPAP titration.

The total time required from the diagnostic process until the start of the CPAP treatment was short in the present study. This reinforces that the use of portable monitors and remote home titration is a viable and effective alternative for early therapy initiation. However, the CPAP comes with some inconveniences or drawbacks (noise, pressure exerted on the face etc.), and the adaptation may be difficult for the patients, as showed by the 9.1% of patients that withdrew from or were non-compliant to the treatment. Furthermore, available data suggest that compliance ranges from 40% to 85% and may be affected by many factors,[18] reinforcing the need for strategies to optimize compliance.

In the present study, patients who completed the 90-day follow-up showed good compliance (74.3%) and a mean daily use of 6 h per night. The early identification of patients who have difficulties with the therapy and the fact that it enables rapid interventions may explain how telemonitoring can improve CPAP compliance. In agreement with our findings, Hoet et al.[19] demonstrated that telemonitoring delays the first intervention and was the factor associated with improved compliance in the first three months of treatment. Although conflicting results were published about telemonitoring improving CPAP therapy compliance, its cost-effectiveness was undeniably proven as it prevents unnecessary specialist consultations, reducing health expenses[20] and enabling the effective monitoring of patients who live in remote areas, increasing accessibility to health care.[10]

Table 3 Variables related to CPAP use at 30, 60 and 90 days.

	30 days	60 days	90 days	*p*-value
AHI (event/h)	1.4 (0.7–2.6)	1.4 (0.7–2.4)	1.4 (0.7–2.3)	0.95
Compliance (%)	79.2	76.3	74.3	0.27
Device use (h/night)	6.2 ± 1.4	6.0 ± 1.4	6.0 ± 1.3	0.59
Leak (L/min)	22.7 (16.1–33.8)	23.6 (15.3–33.2)	24 (15.2–32.6)	0.98

Abbreviations: AHI, apnea-hypopnea index; CPAP, continuous positive airway pressure.
Note: Data are presented as median (interquartile range, IQR) values, mean ± standard deviation values, or as percentages.

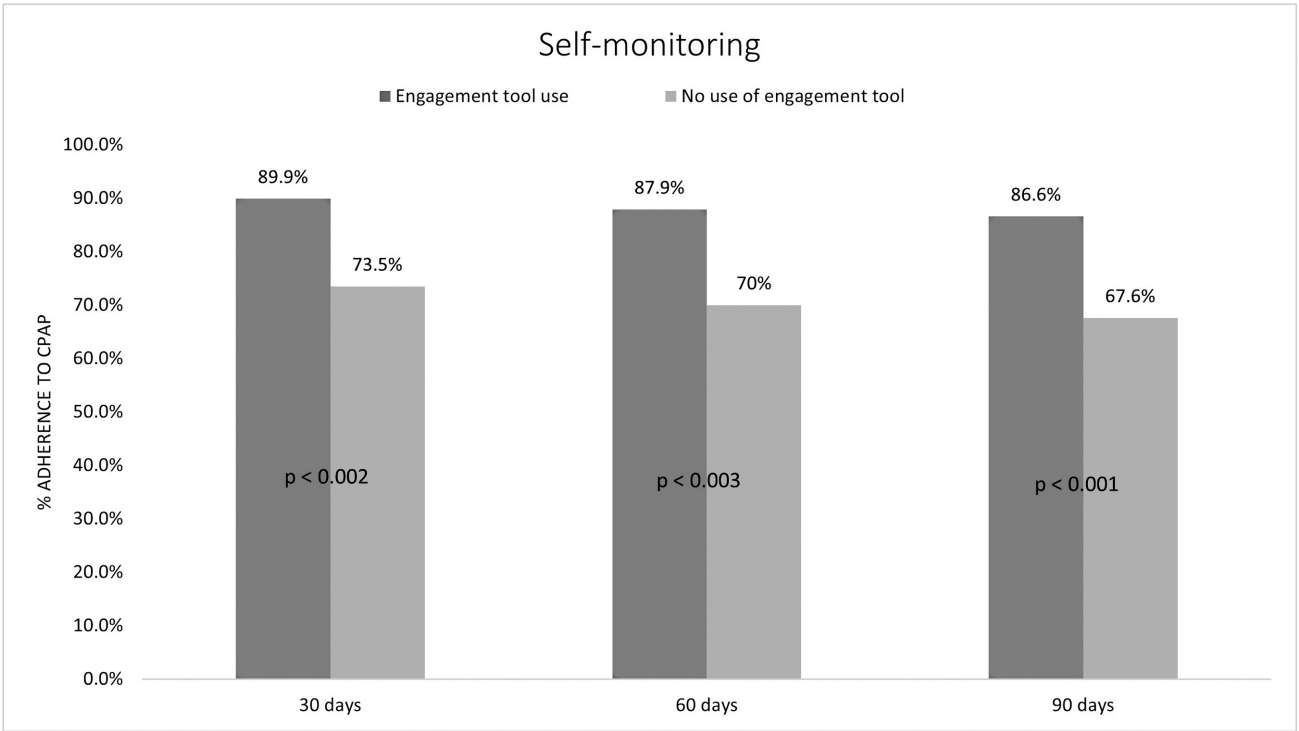

Fig. 2 Patient compliance to the CPAP treatment at 30, 60, and 90 days.

Interestingly, despite the guidance and encouragements provided, few patients used the engagement tool. However, those who used it showed better compliance to treatment, supporting the fact that the use of tools to promote patient engagement is essential. The big data study by Drager et al.[21] supports our findings by emphasizing the importance of telemonitoring and particularly the use of self-monitoring application to improve patient compliance to the treatment. Nevertheless, it is noteworthy that elderly patients may have difficulties using this tool.

The present study has limitations that should be addressed, such as the fact that it was conducted at a single center, in a private clinic, with a small sample size. Furthermore, it is important to highlight that we recruited patients with moderate to severe OSA, and data regarding sleep test losses and discomfort were not collected. However, the good CPAP compliance and rapid diagnosis and treatment initiation observed are the strengths of the present study.

Conclusion

We demonstrated that an alternative in-home protocol to diagnose and treat OSA is effective, ensuring good CPAP compliance after 90 days. We also demonstrated that telemonitoring and engagement tools for patient compliance to the CPAP treatment could be used in the routine practice.

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Conflict of Interests
The authors declare a potential conflict of interest due to the fact that the study was sponsored by ResMed® Corp.

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