Patient Intolerance and Compliance with Positive Airway Pressure Treatment Outpatient Consultations Profile in a Sleep Unit

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Abstract

Introduction: Treatment with positive pressure may cause adverse effects. In order to know the compliance and intolerance profile, we analyzed the behaviors established by physiotherapists of a Sleep Unit.

Materials and Methods: Observational, retrospective, cross-sectional study. We included patients older than 18 years with positive pressure referred to the kinesiological consultation.

Results: 244 patients were evaluated during four years: 165 men (67%), age 65.7 ± 11.6 years, BMI (Body Mass Index) 31.0 ± 5.4 (kg/m2), 61% of which used fixed CPAP (Continuous Positive Airway Pressure), 29% auto-adjusting CPAP, 8% bilevel devices, 147 (60%) nasal masks, 52 (21%) oronasal masks; 37 pads (15%), and 92 (36%) thermohumidifiers.

Reasons for consultation were: therapy control, 239 (61%); intolerance, 67 (17%), and calibration, 51 (13%).

Compliance (hours/night) was 4.61 ± 2.1, with a percentage of nights > 4 hours of 67 ± 36%. We didn't find any difference in the compliance of the first and the second year (4.5 vs. 5.0 hours/night) p > 0.13, but the value was higher after 600 days of therapy (p < 0.05). 141 patients (57%) showed some complications, the most frequent being leaks (19%) or intolerance to the masks (10%). 97% of the patients resolved the intolerance with 194 behaviors: explanation of how to use the mask, 94 (48%); calibration, 44 (22%); information, 45 (23%); titration, 13 (6%), and referral to the pulmonologist, 14 (7%).

Conclusions: Two thirds of the patients complied with the positive pressure treatment and half of the patients showed intolerance. The specialized kinesiological consultation can contribute to the identification and resolution of difficulties that may arise during therapy.

Key words: Sleep apnea syndrome; CPAP treatment; adherence

Introduction

CPAP therapy is the first-line treatment of moderate and severe sleep apneas of obstructive mechanisms (OSA)[1-2]. Its efficacy depends on the compliance and intolerance of multifactor origin, which are frequent in the initial phases of treatment[3-7].

A multidisciplinary team is essential to contribute to the treatment with continuous positive airway pressure (CPAP) in patients with sleep-related breathing disease. Personalized care and a precision medicine approach determine that the treatment should take into account the preferences and individual responses to treatment[8-13].

Various studies show that health professionals other than physicians may have a broad and diverse role during follow-up and clinical management of patients with OSA or patients who require CPAP

or noninvasive ventilation (NIV)[8-12]. The education of patients and treatment follow-up are important tasks in this regard[10-12] as well as the identification and resolution of the main secondary effects[3, 12, 13].

On the other hand, the CPAP devices record data that allow for the evaluation of the patients' performance by monitoring compliance, leaks, the level of therapeutic pressure and residual events. This is a useful way of evaluating efficacy with time and through different interventions[8-14] and the devices are crucial to the identification of intolerance.

With the aim of knowing the level of compliance, the consultation profile, and causes of intolerance, we proposed to analyze the behaviors determined in a Sleep Unit through a specialized consultation unit conducted by physiotherapists.

Objectives

– To know the level of compliance, the causes of intolerance to CPAP treatment and the behaviors determined for its resolution.

Materials and Methods

Study Design
Observational, retrospective, cross-sectional study in only one center.

We reviewed systematically collected data of outpatient consultations between January 2016 and January 2020, obtained from a medical office specialized in CPAP adaptation and follow-up that belongs to the Sleep Unit of a community hospital.

This study was approved by the Institutional Review Board of the Hospital Británico (CRIHB, for its acronym in Spanish) in accordance with the ethical principles of the Declaration of Helsinki and successive amendments (CRIHB #1030 protocol, approved on 15 August, 2020).

Population
The study included OSA patients older than 18 years who were evaluated in the sleep medicine specialized consultation unit coordinated by a respiratory physiotherapist. Patients were referred for monitoring of CPAP treatment, education and training in the use of the device or demonstration of how to use the interfaces.

We took into account the consultation of patients without previous experience and also those who had completed the adaptation; also, patients diagnosed with obesity hypoventilation syndrome, periodic breathing and those requiring other modes of treatment with positive pressure (ventilation with two levels of pressure, servo-controlled ventilation).

During the daily physiotherapist consultation, the indication of CPAP therapy or noninvasive ventilation given by the respective attending pulmonologists was kept the same with no modification or intervention, as usually happens in our Sleep Unit.

Patients who didn't need positive pressure treatment or suffered another sleep-related, non-respiratory disease were excluded.

Information regarding compliance, efficacy and tolerance to CPAP/NIV therapy
The baseline Apnea-Hypopnea Index (AHI) was obtained from the polysomnography (PSG) or respiratory polygraphy (RP) records, and the Body Mass Index (BMI) was registered from the sleep study reports.

We took into consideration the information received during the patients' consultation with regard to: reason for consultation, duration of therapy, mean use and percentage of nights with > 4 hours' use in the last 30 days, and intolerance events related to the devices told by each patient (pressure, auto-perceived leaks and humidification level of inhaled air).

Objective follow-up data were obtained from the information downloaded from the devices' memory (SD Card) by means of the following software: Encore™ Pro II Philips-Respironics™, ResScan™ of

ResMed™, ResSmart™ of BMC Medical™, or else by means of the online Air View™ platform (remote monitoring) of ResMed™.

We confirmed the masks that were used and the main adverse effects or lesions related to the interfaces.

Information about the effective pressure was obtained from the visual analysis of the pressure/time curve. When available, data regarding compliance, mean leaks and residual apnea-hypopnea index (rAHI) were registered in events per hour (ev/h).

Statistical Analysis

Data were presented as percentages of the categorical variables. Continuous variables with normal distribution are expressed as number and percentage (n; %) or mean and standard deviation; and variables without normal distribution are expressed as median and percentile (25-75%).

For the comparison of differences, we used the Mann-Whitney or Fisher tests or χ^2, depending on the type of variables. For the comparison of different therapy pressures, we carried out a linear regression analysis. For the statistical analysis we used Graph Pad Prism-8.02™ software.

Results

244 patients were evaluated in 388 visits for four years. 165 patients were men (67%); age, 65.7 ± 11.6 years, BMI (kg/m²) 31.0 ± 5.4. **Table 1** summarizes the characteristics of the study population.

TABLE 1. Characteristics of the population under study

Patients	n: 244
Men	165 (67%)
Age (years)	65.7 ± 11.6
BMI (kg/m²)	31.0 ± 5.4
Diagnosis obtained by respiratory polygraphy	124 (50%)
Diagnosis obtained by polysomnography	105 (43%)
Mild OSA	6 (2%)
Moderate OSA	66 (27%)
Severe OSA	155 (63%)
Other sleep-related respiratory disorders	17 (7%)
> 1 year since the beginning of the treatment	53 (21%)
< 1 year since the beginning of the treatment	102 (41%)
CPAP treatment initiation visit	89 (36%)
Devices	
Fixed pressure CPAP	151 (61%)
Autoadjusting CPAP	72 (29%)
Bilevel device	21 (8%)
Interfaces	
Nasal	147 (60%)
Oronasal	52 (21%)
Pad	37 (15%)
Use of humidifier	92 (36%)

(n; %): percentage and number of patients. (±): values expressed as mean and standard deviation
BMI: Body Mass Index. OSAHS: obstructive sleep apnea/hypopnea syndrome. CPAP: continuous positive airway pressure. Bilevel: therapy with two levels of positive pressure.

The diagnosis was established by polysomnography (43%), home respiratory polygraphy (50%) or both (6%). Six patients showed mild OSA (2%), 66 (27%) had moderate OSA and there were 155 cases (63%) of severe OSA. 7% were respiratory sleep-related diseases other than OSA.

At the moment of the consultation, 61% of patients used fixed pressure CPAP, 29% auto-adjusting CPAP and 8% bilevel devices. At the moment of the evaluation, 147 patients used nasal masks (60%); 52 oronasal masks (21%); 37 pads (15%), and 92 patients (36%) used thermohumidification systems.

53 (21%) patients had undergone more than 1 year of treatment with positive pressure devices; less than one year, 102 patients (41%); and 89 patients started treatment with kinesiological support (36%).

After analyzing the visits (more than one per patient), we found out that the reasons for consultation were mainly therapy control (239; 61%), intolerance (67; 17%) and CPAP calibration (51; 13%). **Table 2** shows the reasons for referral and initial consultation.

TABLE 2. Frequent reasons for referral to kinesiological consultation

Consultations*	n: 388
Therapy control	239 (61%)
Therapy difficulties	67 (17%)
CPAP calibration	51 (13%)
Use of the mask	22 (5%)
Education	9 (2%)

*Number of cases and percentage.

Compliance with positive pressure treatment (hours/night) was 4.6 ± 2.1, with a proportion of nights > 4 hours of use for 30 days before consultation of 67 ± 36%. 94 patients (38%) showed compliance with > 75% of the nights. **(Table 3)**

TABLE 3. Data of therapy and compliance as from the download of software in the devices (*built-in software*)

Average use (hours/night)	4.6 ± 2.1
Use > 4 hours/night (%)	67.6 ± 36.1
Residual AHI (ev/hour)	7.3 ± 10.8
Leaks (liters/minute)	25.3 ± 19.1

Residual AHI: residual apneas index. Ev/hour: events per hour of therapy.

We didn't find any difference in compliance when comparing the first and second year of CPAP use (4.5 vs. 5.0 hours/night) $p > 0.13$ (Figure 1). However, the percentage of nights using the device > 4 hours was higher relating to longer duration of therapy, evidencing this difference 600 days after starting the treatment **(Figure 2)** $p < 0.05$.

141 patients (57%) showed intolerance, most frequently leaks (42; 19%) and events related to the mask or thermohumidification **(Table 4 and Figure 3)**. In 138 cases (97%), the intolerance could be identified and resolved during the kinesiological consultation.
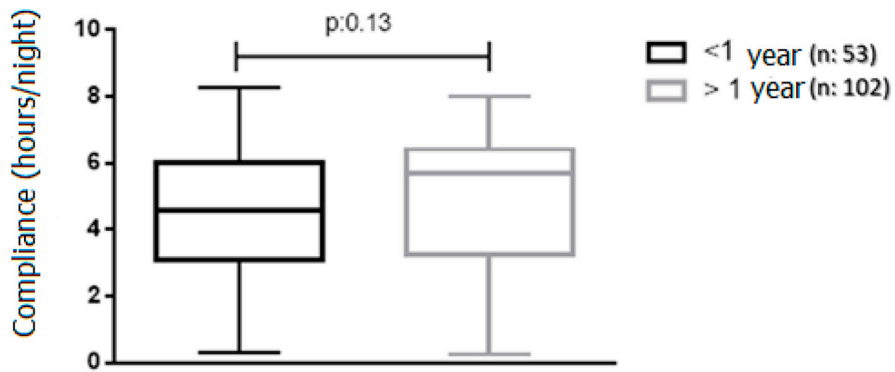
Figure 1. Compliance ≥ 4 hours/night regarding duration of treatment with positive pressure (< 1 vs. ≥ 1 year).
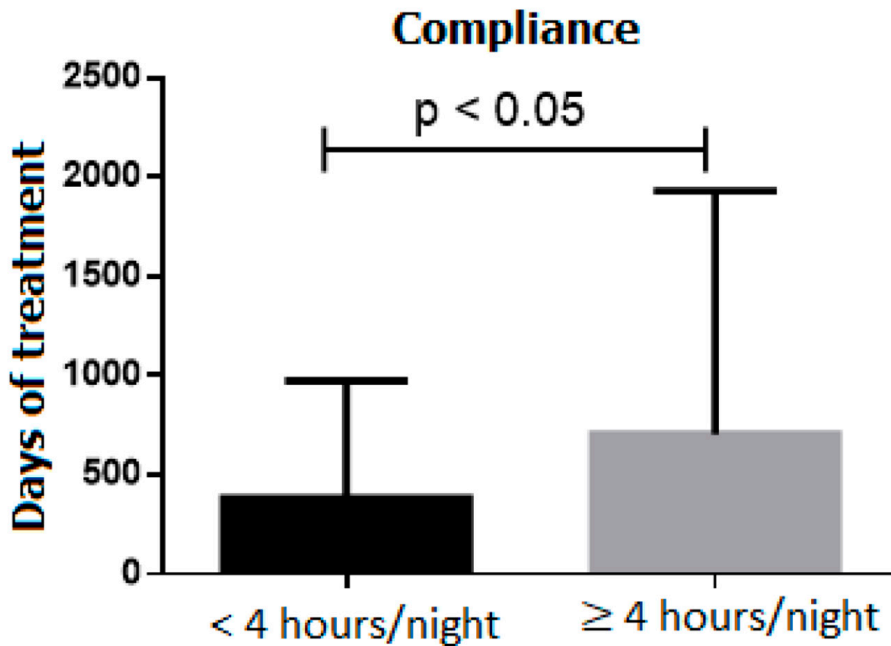

Figure 2. Minimum compliance (> or < 4 hours/night) regarding the duration of treatment.

TABLE 4. Causes of intolerance after kinesiological evaluation

No intolerance	103 (42%)
Identified intolerance	141 (57%)
Leak	42 (19%)
Dry mouth	15 (6%)
Excessive pressure	23 (9%)
Irritation caused by mask	16 (6%)
Pressure sore	9 (3%)
Nasal congestion	13 (5%)
Other	17 (7%)

*Number and percentage of causes of intolerance.
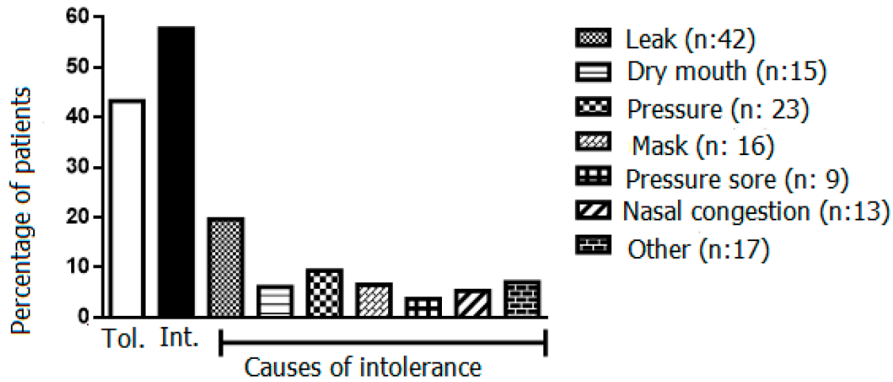
Data expressed over the total number of visits with identified cause of intolerance.

Figure 3. Main causes of intolerance to treatment with positive pressure.

Within the group with > 1 year of treatment (n; 53), 36 patients showed intolerance (67%), though 34 (64%) complied with the therapy more than 4 hours/night and 30 (56%) complied with > 4 hours of use, > 75% of the nights, within 30 days before consultation. **(Table 5)**

TABLE 5. Compliance and intolerance profile in patients with > 1 year of treatment

CPAP treatment > 1 year*	53 (21%)
Intolerance	36 (67%)
Use > 4 hours/night	34 (64%)
> 4 hours' use, 75% of nights, the last 30 days	30 (56%)

*Number and percentage. CPAP: Continuous Positive Airway Pressure.

Finally, 194 behaviors were determined for the resolution of intolerance events detailed in **Table 6**.

TABLE 6. Interventions determined for the resolution of intolerance events

Behaviors*	194 (49%)
Explanation of how to use the mask	94 (48%)
Changes in work pressure or calibration adjustments	44 (22%)
Education	45 (23%)
Request for a new titration test	13 (6%)
Referral to pulmonologist	14 (7%)
Other	25 (12%)

*Number and percentage of behaviors carried out at the specialized kinesiological consultation.

Discussion

This work exposes the complexity of OSA patients' follow-up during treatment with positive airway pressure.

In our population, one third of patients with CPAP required interventions related to the device or the mask, or needed guidance to follow the treatment, or solve the intolerance or the treatment's adverse effects.

In OSA patients who are in the adjustment or follow-up phase, the work model of our unit takes into account the participation of the respiratory physiotherapist with bi-directional referral to and from the pulmonologist. Mid-term follow-up (the first six months) is the period in which the main secondary effects are produced, which, if adequately resolved, determine success in terms of acceptance and maintenance of therapy in the long-term[12]. The role of the non-medical staff at the Sleep Unit may be a control point in the semiology of the patient and his/her equipment, and include sleep lab technicians, nurses and physiotherapists.

In this cohort of patients, compliance was acceptable (near 70%), with a mean use > 4 hours/night similar to that described in other works, both national and international[16-20]. However, thanks to specialized consultations it was possible to identify frequent events of intolerance and create positive feed-back that lets the patient and the attending staff interact in order to solve them[3].

The most predominant reason for consultation was referral for treatment adherence control. Objective data about compliance are fundamental for making decisions during follow-up[11-14]; but the clinical evaluation allowed for the identification of intolerance events, a predictive factor for treatment withdrawal, even in patients who consulted about daily data download from the device.

It has been suggested that in our country the poor contact with the reference hospital complicates CPAP treatment continuity[21]. There is low quality preliminary evidence regarding the granting of equipment, thus the monitoring clinical work is hierarchically organized in reference units[22].

Also, other frequent clinical problems were identified: allergic or irritable rhinitis, insomnia and bad sleep hygiene, which motivated referrals to the respective attending physicians, ensuring multidisciplinary work[3,12,13].

Published data exposed the fact that the first 2-4 weeks after the start of treatment with positive pressure are crucial for favoring adherence, since it is during this period that intolerance is frequently identified[3]. However, we could identify lower adherence in patients with > 1 year of CPAP (traditionally considered as adapted to therapy), as described by Morrone et al, who showed 67% compliance > 5 hours/night after 1-year follow-up in a protocolized environment[15]. Surprisingly, in this series, the differences in the compliance profile could be seen after 600 nights of treatment, exposing the need to continue follow-up and analysis of intolerance beyond the first year.

Procedures during the stages of adaptation, titration, and monitoring of compliance and efficacy of positive pressure require specific instruments[3,14] (software management, knowledge of different therapy devices, use of masks, knowledge of cognitive-behavioral strategies, understanding of sleep questionnaires, standardized clinical behavioral protocols, etc.), which turn the kinesiological consultation into a current discipline that is part of those conforming the multidisciplinary team that must offer solutions for OSA and related disorders[23].

Finally, our work is retrospective and includes the typical limitations of this type of design. Also, attendance to this model of specific consultation depends on medical referral, representing a bias and a limitation that complicates interpretation and doesn't allow the extrapolation of results to other systems of organization.

Conclusions

Two thirds of OSA patients evaluated in a clinical interview by physiotherapists use positive pressure more than 4 hours per night, and half of the patients show intolerance even after the period of adaptation.

The specialized kinesiological consultation may contribute to the identification and resolution of

difficulties, applying a protocol based on education and training, interface selection and mid- and long-term follow-up.

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References

1. Nogueira F, Nigro C, Cambursano H, Borsini E, Silio J, Avila J. Practical guidelines for the diagnosis and treatment of obstructive sleep apnea syndrome. Medicina (B Aires). 2013; 73(4): 349-62.
2. Grupo Español de Sueño. Documento consenso español sobre el síndrome de apneas-hipopneas del sueño. Arch Bronc. 2005;41(Supl 4): 7.
3. Nogueira JF, Borsini E, Nigro C. Estrategias para mejorar la adaptación al tratamiento con CPAP en pacientes con SAHOS. Rev Am Med Resp. 2016; 4: 365-77.
4. Lewis KE, Seale L, Bartle IE, Watkins AJ, Ebden P. Early predictors of CPAP use for the treatment of obstructive sleep apnea. Sleep. 2004; 27(1): 134-8.
5. Budhiraja, R, Parthasarathy S, Drake CL, et al. Early CPAP use identifies subsequent adherence to CPAP therapy. Sleep. 2007; 30(3): 320-4.
6. Lim DC, Pack AI. Obstructive Sleep Apnea: Update and Future. Annu Rev Med. 2017; 68: 99-112.
7. Lévy P, Kohler M, McNicholas WT, et al. Obstructive sleep apnoea syndrome. Nat Rev Dis Primers. 2015;1: 15015.
8. Gong F, Chen X, Wu Y, et al. Nurse vs. physician-led care for obstructive sleep apnoea: A systematic review and meta-analysis of randomized trials. J Adv Nurs. 2018; 74(3): 501-6.
9. Patout M, Arbane G, Cuvelier A, Muir JF, Hart N, Murphy PB. Polysomnography versus limited respiratory monitoring and nurse-led titration to optimise non-invasive ventilation set-up: a pilot randomised clinical trial. Thorax. 2019; 74(1): 83-6.
10. Valerio TD, Heaton K. The effects of an online educational program on nurse practitioners' knowledge of obstructive sleep apnea in adults. J Am Assoc Nurse Pract. 2014; 26(11): 603-11.
11. Suarez-Giron M, Bonsignore MR, Montserrat JM. New organisation for follow-up and assessment of treatment efficacy in sleep apnoea. Eur Respir Rev. 2019; 28(153).
12. López-López L, Torres-Sánchez I, Cabrera-Martos I, Ortíz-Rubio A, Granados-Santiago M, Valenza MC. Nursing Interventions Improve Continuous Positive Airway Pressure Adherence in Obstructive Sleep Apnea With Excessive Daytime Sleepiness: A Systematic Review. Rehabil Nurs. 2020; 45(3): 140-6.
13. Sánchez-de-la-Torre M, Barbé F. Personalized medicine in sleep apnea: Towards a new paradigm of comprehensive disease management. Med Clin (Barc). 2016; 147(10): 444-6.
14. Shelgikar AV, Durmer JS, Joynt KE, Olson EJ, Riney H, Valentine P. Multidisciplinary sleep centers: strategies to improve care of sleep disorders patients. J Clin Sleep Med. 2014; 10(6): 693-7.
15. Morrone E, Giordano A, Carli S, et al. Something is changing in adherence to CPAP therapy: real world data after 1 year of treatment in patients with obstructive sleep apnea. Eur Respir J. 2020; 55(3): 1901419.
16. Nogueira F, De Luca M, Simonelli G, Vera D, Vera S, Rey R. ¿Qué pasa con los pacientes luego de que se les diagnostica Apneas del Sueño? Rev Am Med Resp. 2007; 2: 41-7.
17. Décima T, Maldonado L, Bosio M, et al. Cumplimiento y abandono de CPAP en pacientes con síndrome de apneas del sueño. Rev Am Med Resp. 2013; 4: 197-206.
18. Nogueira JF, Simonelli G, Giovini V, et al. Access to CPAP treatment in patients with moderate to severe sleep apnea in a Latin American City. Sleep Sci. 2018; 11(3): 174-82.
19. Wolkove N, Baltzan M, Kamel H, et al. Long-term compliance with continuous positive airway pressure in patients with obstructive sleep apnea. Can Respir J. 2008; 15: 365-9.
20. Wang Y, Gao W, Sun M, et al. Adherence to CPAP in patients with obstructive sleep apnea in a Chinese population. Respir Care. 2012; 57: 238-43.
21. Leiva Agüero S, Larrateguy LD, Nogueira F, et al. Tratamiento con presión positiva de la Apnea Obstructiva del Sueño. Posición de la Asociación Argentina de Medicina Respiratoria. Rev Am Med Resp 2019; 4: 332-48.
22. Nogueira JF, Giovini V, Borsini E, et al. Evaluación de la calidad de servicio prestado a pacientes con apneas del sueño por parte de diferentes proveedores de CPAP. Abstract 43º Congreso Argentino de Medicina Respiratoria. Rev Am Med Resp. 2015; Supl1-89.
23. Borsini E, Décima T. ¿Cómo debemos organizar el seguimiento de los pacientes con síndrome de apneas-hipopneas durante el sueño? Rev Am Med Resp. 2014; 2: 187-9.