ORIGINAL ARTICLES

Continuous Positive Airway Pressure Used by Adults With Obstructive Sleep Apneas After Prescription in a Public Referral Hospital in Mexico City

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OBJECTIVE: The aim of this study was to analyze the frequency of initiation of continuous positive airway pressure (CPAP) in patients with obstructive sleep apnea syndrome (OSAS) in a referral hospital in Mexico City serving mainly patients without public health insurance coverage and to assess their level of adherence.

PATIENTS AND METHODS: Patients with OSAS diagnosed by polysomnography or by simplified respiratory polygraphy for whom nasal CPAP was prescribed were enrolled in the study. Titration of CPAP was performed during polysomnography or with an automatic CPAP device. Compliance with treatment was assessed during a medical visit or by telephone interview.

RESULTS: A total of 304 patients were enrolled upon prescription of nasal CPAP; 169 (55.5%) either purchased a device or were provided with one by the social security system. The patients most seriously ill and who had public health insurance coverage were the ones who most often acquired a device. These patients took 1.5 months to obtain the equipment and had a compliance rate of 80% at a mean 34 months of follow-up. The respiratory events index was correlated with compliance, whereas excessive daytime sleepiness (Epworth scale score) and body mass index were predictors of therapeutic CPAP pressure.

CONCLUSIONS: Nearly half the patients who were prescribed CPAP did not acquire the device. Most of those who acquired a device adhered to the treatment. In Mexico access to procedures for diagnosing OSAS is limited and access to treatment is also restricted for patients who do not have public health insurance coverage.

Key words: *Obstructive sleep apnea syndrome (OSAS). Apnea. Therapeutics. Sleep. Continuous positive airway pressure (CPAP). Compliance.*

Uso de CPAP en adultos con síndrome de apneas obstructivas durante el sueño después de prescrpción en un hospital público de referencia de la ciudad de México

OBJETIVO: El propósito del estudio ha sido analizar la frecuencia de inicio de tratamiento con presión positiva continua de la vía aérea (CPAP) y su cumplimiento en pacientes con síndrome de apneas obstructivas durante el sueño (SAOS), en un hospital de referencia de la Ciudad de México que atiende predominantemente a pacientes sin seguridad social.

PACIENTES Y MÉTODOS: Se incluyó a pacientes con SAOS diagnosticados por poliomnografía o poligrafía respiratoria simplificada, a quienes se prescribió CPAP nasal. La titulación de ésta se realizó durante la polisomnografía o con un equipo automático de CPAP. El cumplimiento del tratamiento se evaluó en consulta o por entrevista telefónica.

RESULTADOS: Se incluyó a un total de 304 pacientes con prescripción de CPAP nasal. De ellos, 169 (55,5%) adquirieron el equipo (ya fuera por compra o gratuitamente a través de la seguridad social). Los pacientes más graves y con seguridad social fueron los que más frecuentemente lo adquirieron. Este grupo tardó 1,5 meses en obtener el equipo y tuvo un 80% de cumplimiento a los 34 meses de seguimiento medio. El índice respiratorio se asoció al cumplimiento, mientras que la somnolencia diurna excesiva (puntuación de Epworth) y el índice de masa corporal fueron predictores de la presión terapéutica de CPAP.

CONCLUSIONES: Casi la mitad de los pacientes a quienes se prescribió CPAP no adquirió el equipo. La mayoría de quienes lo adquirieron cumplió el tratamiento. En México, además del limitado acceso a los métodos diagnósticos de SAOS, el tratamiento está restringido en los pacientes diagnosticados que carecen de seguridad social.

Palabras clave: *SAOS. Apnea. Tratamiento. Sueño. CPAP. Cumplimiento.*

Introduction

The treatment of choice for patients with obstructive sleep apnea–hypopnea syndrome (OSAS) is continuous positive airway pressure (CPAP).[1] Use of CPAP treatment lowers mortality in these patients to the rate

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prevailing in the general population[2] and improves quality of life.[3] However, the main problem is poor long-term compliance. Reported compliance ranges from 40% to 90% in different studies,[4-6] a variation that is partly attributable to the criteria used to define the concept.

A point of discussion has been the uneven availability of health care services for OSAS patients, even in developed countries[7] and those with public health care systems.[8] Restricted access is largely due to scarcity of sleep clinics and medical specialists and in a general way to the high level and cost of technology used to study sleep disorders.

Around 45% of the Mexican population does not have public health insurance coverage.[9] These patients therefore seek treatment in designated public hospitals where it is not possible to provide a CPAP device after OSAS is diagnosed. Patients must then purchase their equipment or seek out a charity that will donate one. One Mexican study showed that the cost of health care for a patient with OSAS is around US$1300, including diagnosis by polysomnography and the purchase of equipment to deliver CPAP.[10] This situation can mean that patients do not acquire a CPAP device and therefore do not obtain the benefits of treatment. If the inability to purchase a device is added to lack of compliance, there can develop a situation in which few patients receive the effective treatment that is available. It is important to note that patients with Mexican public health insurance coverage still have limited access to diagnostic and therapeutic procedures for sleep apnea. Some therefore go to certain public hospitals where they are charged for care. To date, most private insurance companies will not pay for CPAP treatment.

The aim of this study was to ascertain the percentage of patients with OSAS who undergo appropriate therapy, acquiring a CPAP device and complying with treatment. Predictors of long-term compliance and of titrated level of therapeutic CPAP were also identified.

Patients and Methods

We analyzed the records of patients who were prescribed nasal CPAP after diagnosis of OSAS at the sleep clinic of the Instituto Nacional de Enfermedades Respiratorias, a Mexico City referral hospital treating patients with respiratory diseases. Most have no public health insurance coverage and live in Mexico City and the surrounding area. Diagnosis was established by standard nighttime polysomnography (Grass-Telefactor, Astro Med Inc, West Warwick, Rhode Island, USA) for most patients (270, 88.8%). In 34 patients (11.2%) a portable cardiorespiratory polygraph (Remmers Sleep Recorder, Sagatech, Calgary, Alberta, Canada) was used to assess arterial oxygen saturation (SaO_2), heart rate, sounds, body position, and nasal airflow. A diagnosis of OSAS was made when the apnea–hypopnea index exceeded 5 or when the polygraphic count of saturations of at least 4% reached a frequency of 15 or more events per recording hour. Previous studies comparing the portable monitor used in this study to conventional nighttime polysomnography have shown that the diagnostic yield of the simple monitor is high.[11] A respiratory events index (REI) referred either to the apnea–hypopnea index or to the number of desaturations, depending on the type of sleep study the patient had undergone.

CPAP titration was carried out during polysomnography (Maestro Clinical Remote, Respironics Inc, Murrysville, Pennsylvania, USA) by experienced technicians. In general terms, the therapeutic pressure was defined when apneas, hypopneas and snoring were eliminated and oxygenation improved during most sleep stages and in any body position. When a patient's diagnosis was established during an unattended sleep study, the therapeutic pressure was determined by an automatic CPAP device (AutoSet, Spirit, ResMed Ltd, Bella Vista, New South Wales, Australia). In these cases, the pressure corresponding to the 95th percentile of recordings in the device's memory was used. The mask was adjusted for comfort and to prevent leaks.

All patients prescribed CPAP received personal instructions on how the equipment worked, how to clean the circuit and mask, and how to position the mask.

Compliance was considered adequate when the device was used for at least 4 hours every night and at least 5 nights every week.[12] That information was obtained by questionnaire.

To determine the time of compliance with treatment, the starting point was the moment of CPAP prescription rather than the date of initiation of treatment in order to obtain more realistic information about treatment access. Failure to acquire a device, often because of its price, is a factor that affects compliance.

The patients were followed by way of medical visits to the sleep clinic. Telephone contact was established with those who had not come to the clinic for 4 months to ascertain whether the patient was still living and using CPAP or to ask about reasons for abandoning treatment and when it was stopped.

In accordance with the recommendations of the American Academy of Sleep Medicine, OSAS was considered severe when the REI exceeded 30 and the score on the Epworth Sleepiness Scale was over 10.[13] Another candidate REI cutoff of 50, also with an Epworth score greater than 10, was analyzed.

Statistical Analysis

Data were expressed with measures of central tendency or dispersion, depending on type of variable. A Student *t* test was used for between-group comparisons of normally distributed numerical data; a Mann–Whitney U test or comparison of proportions was used when the distribution was non-normal. Kaplan–Meier survival analysis was used to study continuation of prescribed treatment (compliance). Cox regression analysis was used to explore factors related to compliance. Covariates included in the models were CPAP pressure, neck circumference, Epworth score, age, some form of public health insurance coverage, REI, educational level, sex, body mass index (BMI), and mean SaO_2 on the night of the sleep study. The same variables were used in a multiple linear regression model to identify predictors of CPAP device acquisition.

Finally, to identify predictors of therapeutic CPAP level titrated, a linear regression model of the following independent variables was constructed: neck circumference, score on the Epworth scale for assessing daytime somnolence, age, and the presence of obesity (BMI >30 kg/m^2). Data were analyzed independently for men and women.

The Stata software package (Stat Version 9.0, Statcorp, College Station, Texas, USA) was used for analyses. Statistical significance was set at a value of P less than .05.

Results

We enrolled 304 patients (206 men) diagnosed with OSAS who attended the clinic between September 2001

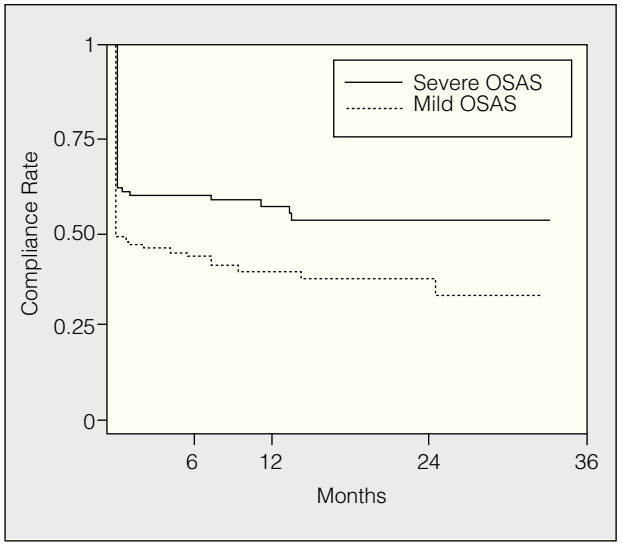

Figure 1. The figure depicts compliance with continuous positive airway pressure (CPAP) in 304 patients with obstructive sleep apnea–hypopnea syndrome (OSAS) stratified by severity of disease. The portion of the patient sample who continued using CPAP (vertical axis) is plotted against time (horizontal axis). The sharp fall at the beginning is the result of patients' failure to initiate treatment. Patients were classified as having severe disease if the respiratory events index was greater than 30 and the score on the Epworth scale was over 10. Analyzing only patients who obtained a CPAP device obtains curves similar to these, though starting from a higher position (at 1 on the y axis).

and July 2004. All were considered candidates for CPAP treatment because of excessive daytime sleepiness (Epworth score >10) or cardiovascular risk. Table 1 shows the characteristics of the population according to whether they did or did not acquire a CPAP device. Patients who acquired the equipment generally had a higher REI and a lower mean SaO_2 during sleep. Logistic regression analysis with device acquisition as the dependent variable showed that the factors that were significantly associated were REI (odds ratio, 1.01; 95% confidence interval, 1.005-1.020) and having public health insurance coverage (odds ratio, 1.71; 95% confidence interval, 1.04-2.83). No differences in compliance were detected between those who were given the device and those who had to pay for it (*P*=.49).

Of the 304 patients prescribed CPAP, 169 (55%) acquired the device either with or without payment. Given the right skewing of the data distribution, we calculated the median lag time until a CPAP device was acquired. Thus, the median delay was 1.5 months (interquartile range, 0.7-4 months).

In the group of 135 patients who did not acquire a device, 47 (34.8%) had severe OSAS (REI >30, Epworth score >10). We also observed that 28 patients had to pay for a CPAP device in spite of being covered by public health insurance (43% of the 65 who purchased a device). Thirty-two of the devices acquired (20.13%) were supplied by the public health insurance system (Instituto Mexicano del Seguro Social); 94 (59.12%) were purchased by the patient or family; 3 (1.89%) were supplied by the government employees' health insurance plan (Seguridad Social al Servicio de los Trabajadores del Estado); 1 (0.63%) was supplied by a family-oriented social welfare group (Desarrollo Integral de la Familia); 8 (5.03%) came from public charities; and 21 (13.21%) were rented.

The figure depicts time of CPAP equipment use from the moment of prescription according to severity of disease (Kaplan-Meier curve). The abrupt initial drop in the curve represents patients who never started treatment. After that drop, acceptable compliance can be observed throughout the follow-up period of 34 months. The shape of the compliance curve drawn for the REI cutoff of 50 as the definition of severe OSAS was similar to that of the curve for the REI cutoff of 30. Six months after prescription the equipment was still being used by 51%; after 12 months the rate of compliance was 47%, after 24 months it was 45%, and after 34 months 43%. Among the patients still using their device, 14 men (14.4%) and 11 women (25.5%) (*P*<.01) used it fewer than 4 hours each night and 5 nights each week. The REI was the only factor that was significantly correlated with treatment compliance, although that association explained only 0.9% of the variance.

The variables that were significant predictors of therapeutic CPAP pressure (Table 2) in the multiple linear regression model were BMI for men and women,

TABLE 1
Characteristics of Patients Who Obtained a Device to Deliver Continuous Positive Airway Pressure (CPAP)*

	Obtained a Device (n=169)	Did Not Obtain a Device (n=135)	*P*
Men	69.8%	65.1%	.42
Age, y	51.2 (13.1)	50.6 (11.4)	.64
Body mass index, kg/m^2	36.7 (7.4)	35.8 (6.2)	.29
Neck circumference, cm	43.2 (4.1)	43.1 (3.6)	.98
Epworth Sleepiness Scale score	12.7 (6.8)	11.6 (6.2)	.15
Obese patients	83.3%	83.4%	1
Patients with public health insurance	41.4%	33.3%	.10
Years of schooling	9.2 (5.6)	8.5 (5.7)	.25
Respiratory events index	61.0 (35.5)	47.4 (32.1)	<.01
Mean SaO_2 at night	81.6 (10.2)	84.5 (6.8)	<.01
CPAP level titrated, cm H_2O	10.6 (2.5)	10.3 (2.3)	.44
Patients with severe OSAS	49.1%	34.8%	<.01

*Data are means (SD) unless otherwise indicated as percentages. SaO_2 indicates arterial oxygen saturation; OSAS, obstructive sleep apnea syndrome. Severe OSAS was defined by a respiratory events index >30 and an Epworth Sleepiness Scale score >10.

TABLE 2
Predictors of Titrated Nasal Continuous Positive Airway Pressure Level According to Multiple Linear Regression*

	Intercept	BMI, Coefficient	Epworth Score, Coefficient	REI, Coefficient	Nighttime SaO_2, Coefficient	R^2	SE
Men							
Model 1†	6.39	0.12				0.09	2.46
Model 2‡	11.9	0.09		0.01	–0.06	0.20	2.33
Women							
Model 1†	5.7	0.09	0.1			0.16	2.05
Model 2‡	5.33	0.07	0.1	0.02		0.25	1.95

*BMI indicates body mass index; REI, respiratory events index; R^2, coefficient of determination; SaO_2, nighttime arterial oxygen saturation.
†Model including the clinical variables. ‡Model including sleep study variables.

and Epworth daytime sleepiness score for women. Table 2 also shows the multiple linear regression models that incorporated mean REI and SaO_2 data derived from the sleep studies.

Discussion

CPAP is currently the standard treatment for patients with moderate or severe OSAS.[1] Use of this treatment has been shown to improve morbidity, mortality, and quality of life for OSAS patients as well as to reduce the excessive daytime sleepiness that is closely related to traffic accidents.[2,3,14] One of the main problems of CPAP therapy, however, is poor long-term compliance rates and the relatively high cost of equipment.[6] A CPAP device costs between US$300 and $1000 in Mexico, a sum that is roughly the earnings of 90 to 260 days at minimum wage. This therapy is therefore unaffordable for a large portion of the population if the cost of the sleep study before prescription is added. Economic difficulty in acquiring a CPAP device represents a potential cause of patient noncompliance with treatment.

Various authors have shown that CPAP use reduces expenditure attributable to the disease.[15,16] However, for a patient, the initial investment is onerous, beyond the means of many individuals and families. We found that 45% of the patients with OSAS who were prescribed CPAP did not obtain devices and therefore never initiated treatment. Thus, we analyzed compliance from the moment of prescription rather than initiation of use, as the latter would have excluded from analysis a considerable number of patients who never started treatment because they had no device. It is not always evident why patients do not obtain CPAP devices, but economic considerations undoubtedly enter into the decision. We were unable to establish a correlation between socioeconomic or educational level and acquisition; nonetheless, although institutional socioeconomic classifications establish various categories, the 4 lower ones to which nearly all the patients in this study pertained, would be considered below the poverty threshold in most countries. The variable associated with acquisition of a device was public health insurance coverage, a finding that indirectly suggests that the cost of equipment is an obstacle. Other associated variables were REI and SaO_2, confirming previously reported observations that the most severely ill OSAS patients are the ones who have additional motivation to obtain a unit.[17] It is noteworthy that our patients who acquired a CPAP device had more severe disease as shown by the REI but did not have significantly different Epworth scores in comparison with those who did not obtain equipment. That is to say, excessive daytime sleepiness does not seem to motivate these patients to make the effort to obtain a device. There are undoubtedly unknown factors that are significantly related, as suggested by the observation that the coefficient of determination in the equation predicting CPAP therapy was 0.25 in the best of cases. Furthermore, obtaining a device does not assure long-term compliance. REI remained independently related to compliance in the Cox regression analysis, as reported by other authors,[17] although the association was weak.

Wild et al[18] described a predictive model for compliance in which clinical, polysomnographic, and psychological variables were considered. The model was only able to explain 24% of the variance in compliance, however. Those results confirm that our understanding of and control over compliance is limited in the setting of chronic treatments.

Of concern is evidence from one study that 35% of patients who never acquired a CPAP device had severe OSAS and were at high risk of complications.[19] It is precisely such patients who benefit most from treatment, as they tend to suffer excessive somnolence and have additional cardiovascular risk factors, such as smoking addiction, hypertension, or dyslipidemia.[19,20] It is important for us to be able to offer consistently affordable treatment alternatives to this group of patients; therefore, after this study we began to call in all patients who were not in treatment.

Health is a constitutional right in Mexico, even though access to health care services is incomplete and highly restricted in the case of the sophisticated techniques required to treat OSAS. We have shown that there were patients who did not use the prescribed treatment even though they were privileged to gain access to the diagnostic procedure. Their reasons are worth considering. Behind the refusal of many to purchase a CPAP device is probably their wish that health care be a public benefit that the state should provide, or their conviction that it should

be so. Furthermore, even under the Mexican public health care system, access to diagnosis and treatment of sleep apnea is limited, just as it is in developed countries, including those with public health services.[7,8] This situation mainly reflects the complexity of the present diagnostic and therapeutic method for sleep apnea and that is what should certainly change. Most patients in this study were diagnosed by polysomnography, a noteworthy observation that sharply contrasts with the economic difficulties many patients face in obtaining a CPAP device. It would therefore be sensible to wonder why resources spent carrying out polysomnography are not directed instead to the purchase of CPAP devices and the simplification of diagnosis through use of portable monitors. The situation is attributable at least partly to the fact that the sleep clinic that undertook the study is a national research and teaching facility engaged in studying sleep disorders. This clinic nevertheless has increasingly shifted its case load to simplified sleep studies.

Finally, it is clear that although CPAP is effective and safe, it is cumbersome, irritating and rather unnatural, and these attributes elicit rejection when first considered by any sensible person. It is also clear that compliance by our patients who managed to obtain a CPAP device was similar to that reported in developed countries: almost 80% of those patients were using the device 34 months after prescription.[5] In an earlier study of 50 patients with severe OSAS, initial compliance with therapy was high immediately after diagnosis when the patients were provided with a CPAP device.[21] Such initial compliance is a predictor of long-term use according to other authors.[22,23] We therefore conclude that providing patients with a CPAP device would be useful for many of them, although it is also undoubtedly necessary to have alternative treatments available. This is particularly so in our practice setting, in the interest of patients and to prevent the wasting of scarce resources that happens when patients undergo a costly diagnostic process and are then left untreated.

As in diseases like asthma, long-term compliance is vitally important and a patient must feel supported by fast, easy access to someone specifically dedicated to solving problems and checking on CPAP use. This prevents and resolves certain problems that can culminate in abandonment of treatment. Thus, a CPAP clinic that work together with other medical and technical staff is needed so that patients will always be able to make contact with the sleep study facility. Resolving doubts and checking on patients, even if only by telephone, helps encourage adherence to treatment. In this way the health injury this disease can cause can be reduced considerably. Our CPAP clinic works well enough for patients who comply with CPAP treatment, but it can be said that the system fails to assure that diagnosed patients receive appropriate treatment.

BMI and REI were identified as predictors of the therapeutic level of CPAP. For women, the Epworth scale score was also a predictor. It may be that men are underestimating their somnolence or that women have a more accurate perception of disability with respect to this symptom. These findings contrast with a report by Baldwin et al[24] that the Epworth scale score had greater sensitivity in identifying daytime somnolence in men than in women.

In the broadest sense, our findings from the practice setting of a Mexican national health facility should lead us to reflect on the use of orthodox methods for diagnosing and treating sleep apnea: even though these methods are effective for controlling apneas,[2,3] they are costly and inconvenient and access to them is still limited. We need a more appropriate approach to reaching the majority of patients who do not yet have either a diagnosis or treatment. Likewise, a major effort is required of the public health system if the impact of obesity and other risk factors for OSAS are to be reduced—to circumvent the need to treat serious and costly complications.

In summary, nearly half the patients without public health insurance coverage who were prescribed CPAP at a referral clinic never started therapy. On the other hand, most patients who obtained a device showed good compliance 3 years later. Patients with public health insurance coverage and those with severe disease were the ones who most often obtained a device, although there was a mean delay of 1.5 months before acquisition. Effective and affordable diagnostic and therapeutic methods—or preventive ones—are needed urgently for OSAS patients in developed countries but even more so in developing ones without universal health care coverage.

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