

Factors Affecting Patients' Adherence to Continuous Positive Airway Pressure Therapy for Obstructive Sleep Apnea Disorder: A Multi-Method Approach

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What's Known

- CPAP is the gold standard therapy for moderate to severe OSA.
- The therapy is only effective if CPAP device is used regularly over a long period of time. However, patients' adherence to its regular use is poor, which in turn poses a challenge to a successful OSA treatment.

What's New

- Factors affecting the adherence rate to CPAP therapy among OSA patients were investigated using both quantitative and qualitative methods.
- Patients could be motivated to regularly use the device through education, follow-up care, and financial support from insurance companies or the government.

Abstract

Background: Continuous positive airway pressure (CPAP) is the gold standard therapy for treating obstructive sleep apnea (OSA) disorder. However, patients' adherence to its regular use is poor. The present study aimed to determine the adherence rate to CPAP therapy by identifying factors affecting its regular use and its associated problems and discomforts among a sample population in Mashhad (Iran).

Methods: The study was conducted from October 2017 to March 2018 in Mashhad (Iran) using both quantitative and qualitative methods. The quantitative study was carried out using a retrospective cross-sectional data collection from five sleep clinics and one CPAP sales office. The patients were classified into an adherent and a non-adherent group to determine the factors affecting CPAP adherence. Quantitative data were analyzed using SPSS software (version 22.0). Additionally, a prospective qualitative study was performed through a series of telephone interviews using the content analysis method. Qualitative data were analyzed using MAXQDA 10 software.

Results: In the quantitative study, the medical records of 159 patients were used, out of which 79 (49.6%) were non-adherent to CPAP therapy. The mean age of all patients was 56.9±9.8 years. The mean body mass index, apnea-hypopnea index, and Epworth sleepiness scale (ESS) scores were 30.9±6.6 kg/m², 37.2±28.1 events/hour, and 10.4±5.5, respectively. At baseline, the adherent group had a significantly higher age (P=0.006), higher oxygen desaturation index (P=0.006), and lower ESS (P=0.023) compared to the non-adherent group. In the qualitative study, a total of 29 telephone interviews were held with patients from the non-adherent group (8 women and 21 men). Analysis of the interviews resulted in three main categories (level of knowledge, discomfort, and costs) and nine sub-categories.

Conclusion: A high percentage of OSA patients had poor adherence to CPAP therapy. Device-related issues could be adequately resolved by providing complementary information during follow-up visits. Moreover, efforts to reduce costs through comprehensive insurance coverage or with government subsidy would improve patients' adherence to CPAP therapy.

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Keywords • Sleep apnea, obstructive • Continuous positive airway pressure • Patient education as topic • Humans • Iran

Introduction

Obstructive sleep apnea (OSA) is the most common sleep respiratory disorder caused by repetitive obstruction of the upper airways during sleep.^{1, 2} Untreated sleep apnea can lead to

cardiovascular diseases, diabetes mellitus, mood disorders, and abnormal daytime sleepiness.³ The severity of sleep apnea is indicated by the apnea-hypopnea index (AHI). The overall prevalence of mild to severe sleep apnea (AHI \geq 5 events/hour) is estimated between 9% to 38%.⁵

Continuous positive airway pressure (CPAP) is the gold standard therapy for treating moderate to severe OSA. The therapy is only effective if the CPAP device is used regularly and over a long period of time.⁶ However, patients' adherence to its regular use is poor and non-adherence is reported at the rate of 34.1%, which in turn poses a challenge to a successful OSA treatment.⁷ Several studies have assessed the association between patients' adherence and demographic as well as clinical factors (sex, age, the Epworth sleepiness scale [ESS], and AHI) and have reported contradictory findings.⁸⁻¹² The various factors that negatively affected patients' adherence to CPAP therapy were device-related issues or the patients' clinical condition (mask type, air leak, skin inflammation, claustrophobia, nasal congestion, and difficulty with exhaling air).^{8, 13-16}

Researchers in various countries have attempted to identify those factors affecting patients' adherence to CPAP therapy in order to design and develop effective interventions for a protracted and frequent use of the device. Regrettably, this issue has not yet been fully addressed in Iran; a developing country with distinct cultural, economic, and social characteristics. To the best of our knowledge, there have been only two studies on patients' adherence to CPAP therapy in Iran.^{17, 18} In these studies, the adherence rate was determined by self-report declarations. However, it is worth mentioning that the true adherence rate is typically lower than that obtained through a self-report survey.^{12, 19} Hence, it is essential to determine a reliable rate and collect a comprehensive set of data on patients' adherence to CPAP therapy among a sample population. Accordingly, the present study aimed to determine the adherence rate to CPAP therapy by identifying factors affecting its regular use and its associated problems and discomforts among a sample population in Mashhad, Iran.

Materials and Methods

The present study was conducted from October 2017 to March 2018 in Mashhad (Iran) using both quantitative and qualitative methods. Both approaches aimed at identifying the factors affecting the adherence rate to CPAP therapy among OSA patients. For clarity, each approach

is described separately.

The study was approved by the Ethics Committee of Mashhad University of Medical Sciences, Mashhad, Iran (code: IR.MUMS.fm.REC.1395.571).

Quantitative Method

Study Design and Participants

A quantitative study was conducted using a retrospective cross-sectional data collection from five sleep clinics and one CPAP sales office in Mashhad, Iran. The medical records of those patients who purchased the CPAP device (ResMed Ltd, Sydney, Australia) during 2014-2017 were obtained from the sleep clinics. In addition, CPAP usage data of all customers were retrieved from the database of the sales office using the ResScan™ software (ResMed Ltd, Sydney, Australia).

The inclusion criteria were the completeness of medical records, the availability of the patients, and AHI \geq 5 events/hours. The exclusion criteria were conditions prohibiting the use of the CPAP device (mental disability) and medical records of deceased individuals. Accordingly, a total of 159 patients were included in the study. It should be noted that none of the patients received follow-up care by the sleep clinics to assess their condition, nor by the sales office to determine proper usage and the functioning of the device.

Data Collection

Demographic and clinical data included age, sex, body mass index (BMI), ESS to quantify daytime sleepiness, polysomnography (PSG) records, and home sleep testing (HST) data. OSA was diagnosed by either full/split-night PSG (level 1) or the ApneaLink™ plus (level 3) diagnostic test. The severity of OSA was classified as mild ($5 \leq \text{AHI} < 15$), moderate ($15 \leq \text{AHI} < 30$), or severe ($\text{AHI} \geq 30$).

CPAP Adherence

The data on adherence rate was retrieved from the microchip embedded in each CPAP device. The microchip monitored and registered the operation and usage of the device. The retrieved data, measured from the first usage of the device, included 9 intervals (days 7, 14, 21, 30, 60, 90, 180, 360, and 540). Note that the initial registration date for each patient was different. Moreover, not all patients activated data storage after each time the device was used. Consequently, the CPAP usage at each interval was calculated based on the available data for each patient. Appendix represents the status of available data in terms of the number of patients and intervals.

In the present study, the term “4-hour adherence” is used as the ratio between the number of specific days (with at least four hours of nightly use) and the total number of usage days. Patients with ≥ 4 hours per night use for at least 70% of the nights were considered adherent. Accordingly, the patients were assigned to an adherent and non-adherent group to determine the factors affecting the adherence rate.

Data Analysis

The statistical analysis was performed using SPSS software (version 22.0). Data were expressed as mean \pm SD or median (interquartile range: 25%-75%). The latter was used for the oxygen desaturation index (ODI), which was not normally distributed based on the Kolmogorov-Smirnov test. Where appropriate, the unpaired *t* test or Mann-Whitney U test was used for comparison between the groups. Categorical data were analyzed using the Chi-square test. $P < 0.05$ was considered statistically significant.

The analysis of the CPAP data was performed using MATLAB software (version 8.1). Curve estimation regression was applied to determine a possible curvilinear relationship between the 4-hour adherence rate at each interval (dependent variable: Y) and the total number of usage days (independent variable: X) using a cubic polynomial function $Y = b_0 + b_1X + b_2X^2 + b_3X^3$. Note that the cubic polynomial function was selected based on the preliminary examination of various curve estimation regression models and choosing a function with the best fit (R^2).

Qualitative Method

Study Design and Participants

A prospective qualitative study was carried out through a series of telephone interviews using the content analysis method. The participants were those patients identified as non-adherent in the quantitative analysis.

Data Collection

The data were collected through 29 individual in-depth semi-structured interviews.

Prior to the interviews, the research goals and methods were explained and voluntary participation was emphasized. Verbal informed consent was obtained from all the participants.

Based on the information obtained from the quantitative method, each participant was provided with a detailed status of his/her usage of the CPAP device. In order to identify the factors affecting the use of the device, a number of targeted questions were asked (e.g., *What prevents you from using the CPAP*

device regularly?). Depending on the response of the participants, additional questions were asked to clarify the responses and to extract complementary information.

Data Analysis

At the end of each interview, the data were transcribed using Microsoft Word software. After a thorough study of the transcriptions, initial codes were obtained and classified in terms of similarities. Classifications were then grouped into categories and sub-categories using the content analysis approach. Data analysis was performed using MAXQDA software version 10.

Results

Quantitative Method

The medical records of 159 patients were used, 69 (43.4%) of which were from female patients. The mean age of the patients was 56.9 ± 9.8 years. The mean BMI, AHI, and ESS score were 30.9 ± 6.6 kg/m², 37.2 ± 28.1 events/hour, and 10.4 ± 5.5 , respectively. Out of the 159 patients, 79 (49.6%) were non-adherent to the CPAP therapy. At baseline, the adherent group had a significantly higher age ($P = 0.006$), higher ODI ($P = 0.006$), and lower ESS ($P = 0.023$) compared to the non-adherent group. Moreover, there was a significant relationship between the adherent and non-adherent group in terms of the AHI severity ($P = 0.005$). As shown in table 1, the number of patients with mild OSA was lower in the adherent than in the non-adherent group. Whereas the number of patients with severe OSA was higher in the adherent than in the non-adherent group. Women were more adherent than men ($P = 0.02$).

The average rate of 4-hour adherence at each interval, for all patients, is shown in figure 1. A significant regression ($F[3, 5] = 5.56$, $P = 0.046$) was found while determining the curvilinear relationship between the 4-hour adherence rate at each interval and the total number of usage days. The results of the curve estimation regression and the associated plots are shown in table 2 and figure 2, respectively.

Qualitative Method

A total of 29 telephone interviews, with an average duration of 20 minutes, were held with the non-adherent patients (eight women and 21 men). Analysis of the interviews resulted in three categories (level of knowledge, problems and discomfort, and costs) and 9 sub-categories as the main factors affecting patients' adherence (table 3).

Table 1: Demographic and clinical characteristics of Obstructive sleep apnea patients

Variable		Adherent (n=80)	Non-adherent (n=79)	P value
		Mean±SD		
Age (years)		59.13±9.30	54.90±9.91	0.006 ^a
BMI (kg/m ²)		31.87±7.72	29.95±4.80	0.067 ^a
ESS total score		9.18±4.98	11.88±6.03	0.023 ^a
		Median (IQR: 25-75)		
ODI (events/h)		42 (19-63)	21 (11-46)	0.006 ^b
		Number (%)		
Sex	Men	38 (42.2)	52 (57.8)	0.020 ^c
	Women	42 (60.9)	27 (39.1)	
Type of test	PSG	52 (55.3)	42 (44.7)	0.129 ^c
	HST	28 (43.1)	37 (56.9)	
AHI (events/h)	Mild	8 (25)	24 (75)	0.005 ^c
	Moderate	24 (53.3)	21 (46.7)	
	Severe	48 (58.5)	34 (41.5)	
Mild AHI	PSG	5 (50)	5 (50)	0.028 ^c
	HST	3 (13.6)	19 (86.4)	
Moderate AHI	PSG	9 (45)	11 (55)	0.316 ^c
	HST	15 (60)	10 (40)	
Severe AHI	PSG	38 (59.4)	26 (40.6)	0.771 ^c
	HST	10 (55.6)	8 (44.4)	

*P<0.05, ^aUnpaired t test, ^bMann-Whitney U test, ^cChi-square test; Mild: 5≤AHI<15, Moderate: 15≤AHI<30, Severe: AHI≥30, BMI: Body mass index, ESS: Epworth sleep score, ODI: Oxygen desaturation index, AHI: Apnea-hypopnea index, PSG: Polysomnography, HST: Home sleep testing

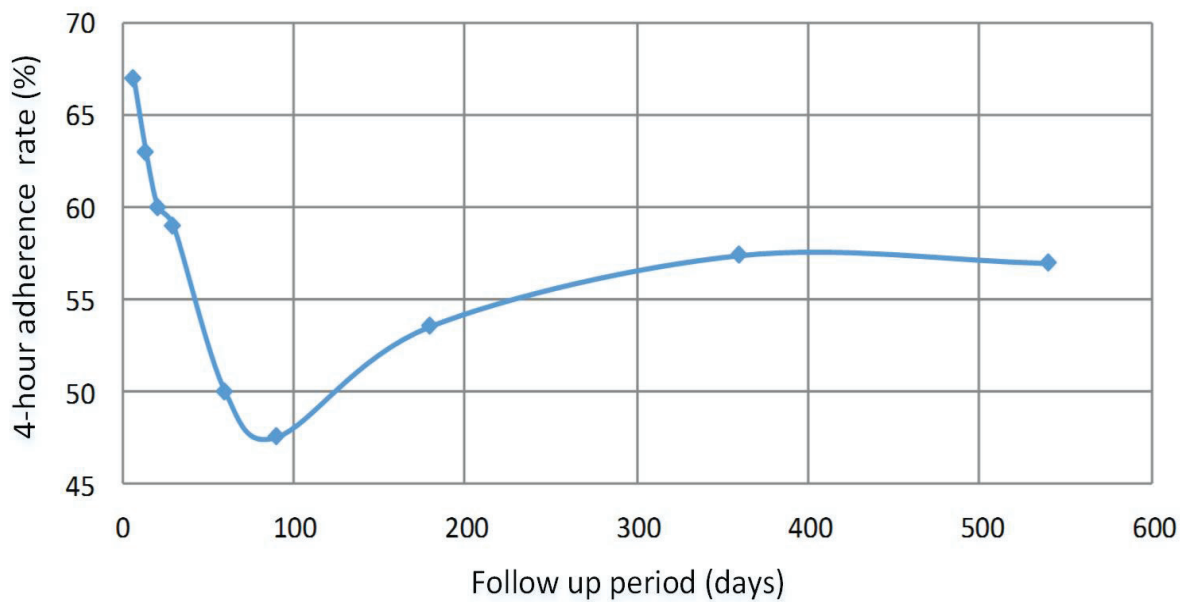


Figure 1: The average rate of 4-hour adherence rate (%), for all patients, with respect to the total number of usage days is shown.

Table 2: The results of the curve estimation regression

Equation ^a	Parameter estimates					
	b ₁		b ₂		b ₃	
	Unstandardized coefficients		Unstandardized coefficients		Unstandardized coefficients	
	B	Std. error	B	Std. error	B	Std. error
Cubic ^b	-0.259	0.065	0.001	3.14E-4	-1.2E-6	3.8E-7
		0.01*		0.016*		0.024*

*P<0.05, ^a4-hour adherence rate=65.7-0.259 (day)+0.001(day²)-1.235E-6 (day³), ^bR²_{cubic}=0.77, P=0.046

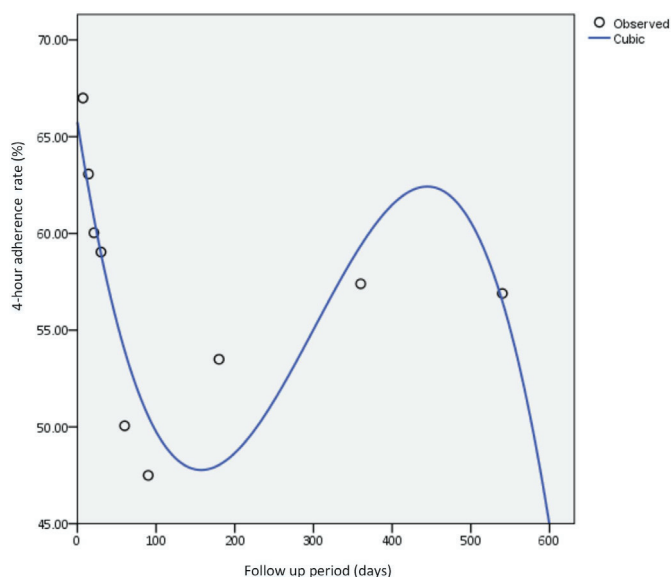


Figure 2: The figure shows curve fitting of the data points using a cubic polynomial function.

Table 3: Extracted categories and subcategories from the in-depth semi-structured interviews, including quotations from the participants

Category	Sub-category	Quotations from the participants
Knowledge level	Lack of knowledge about the essence of the therapy	After a year of consistent use of the device, I felt so much better and therefore I stopped using it.
	Lack of knowledge about the recommended usage	I use the device from the time I go to bed till I wake up for morning prayers. I think this is sufficient nightly use of the device. I bought the device three months ago. I only used it a few times, but not over the required period as it caused discomfort. I noticed some improvements in my condition and thus stopped using it.
	Lack of knowledge about maintenance	The mask has not been working properly for a while. The device had a very positive effect on my health. I should use it more, but recent malfunctions prevented me from doing so.
	Lack of knowledge about the follow-up procedure	During the initial nights of using the device, I felt as if I was suffocating. I did not mention this to my doctor nor the supplier, as I felt they would not be able to help me. I sometimes had difficulties adjusting the device's pressure and temperature. Since I could not go back to the company, I expected them to provide regular follow-up and after-sales support to resolve possible problems.
Problems and discomfort	Difficult to use during traveling	I travel a lot and I cannot take the device with me. Consequently, I am not able to use the device during these periods. On the other hand, I try to minimize the use of the device at home to prevent getting into the habit of using it regularly.
	Mask problems and discomfort (poor fit, air leak, skin marks and irritation, pain, itch, and sweat)	I sometimes do not use the device since the mask shifts when I roll in bed. It blows air into my face and wakes me up. At times my face gets sweaty and the mask shifts, causing the air blowing into my face. This flairs up my sinusitis. When I wake up in the morning, there are mask marks on my face. I dislike attending business meetings with these mask marks. That is why I decided not to use the device the nights before a scheduled meeting.
	Feeling of suffocation	Since day one of usage, I felt as if I was suffocating. I tolerated it for a few hours, but I could not go back to sleep again. I tried to cope with the device for a few more nights, but I did not manage to get any sleep. This is why I completely stopped using it.
	Dry throat	My throat got so dry that it was really hard for me to keep on using the device.
Costs	Inability to cover additional costs for accessories	It has been a few months since my doctor advised me to replace the mask, but due to the cost, I have not done it yet. My doctor advised me to use a humidifier to deal with the dry throat, but I could not afford it.

Discussion

The results showed that the 4-hour adherence rate during the first week of using the CPAP device was about 67%, which decreased to 47% after three months. The rate would have been noticeably lower if the 4-hour adherence for patients without follow-up was set to zero. The results also showed that about 50% of the patients used the CPAP device for more than four hours per night for at least 70% of the nights.

Lack of knowledge about the disorder as well as on the proper operation of the device could have been the reason for a relatively low adherence rate among the patients. Some participants stated that they were not trained on how to operate the device, were unable to resolve malfunctions, and there was no follow-up care nor after-sales support. As a direct result, they simply stopped using the device. Such statements clearly indicated the importance of follow-up care by the treatment team, particularly during the initial days of usage. Other studies have also reported that patient adherence during the first week of CPAP therapy resulted in better long-term adherence.^{20, 21} Salepci and colleagues reported that the adherence rate over one month was about 64.5% among a sample Turkish population who attended follow-up training and received after-sales support.¹² Similarly, among a sample Chinese population, Hui and colleagues reported an adherence rate of 75% and 72% over a 1-month and 3-month period, respectively.²² Such high rates were mainly due to regular follow-up care by nurses and training materials provided by the suppliers.

In line with a previous study,²³ our results from the curve estimation regression analysis indicated that patient adherence was low at two stages of the CPAP therapy, namely the initial phase and approximately a year later. The results underlined the importance of appropriate intervention at the right time. Adequate training would also enable the patients to overcome the challenges associated with the inconveniences of the device. Patients would be motivated to regularly use the device when they become aware of the potentials of the CPAP therapy in treating OSA as well as its long-term benefits compared to its inconveniences. Implementing educational and psychological interventions to elevate patients' awareness and to address their concerns could tremendously increase the rate of patient adherence.^{17, 24, 25}

Lack of comprehensive Iranian insurance coverage for diagnostic tests, the CPAP device, and its accessories were the additional limiting factors that affected the adherence rate. Some

participants were unable to cover the additional costs of the CPAP mask. Consequently, the device did not operate optimally, and its use was reduced. Other studies also reported the impact of socioeconomic status and education level on the adherence rate.^{11, 26-28} In this regard, it was recommended to improve patients' knowledge and facilitate financial support, for at least part of the diagnostic and therapeutic costs, by insurance companies, charities, or through government funding.¹⁷

Our results showed that the AHI and ODI levels were significantly higher in the adherent than the non-adherent group. Note that AHI and ODI are closely related parameters and describe the same aspects of the severity of the disorder. In line with other studies,^{29, 30} we also found that patients with severe OSA better adhered to the CPAP therapy. The results showed a significant difference in the ESS score between the adherent and non-adherent group; indicating a positive relationship between ESS and patients' adherence. However, some other studies^{12, 20, 23} have reported contradictory findings. The difference could be due to the fact that ESS self-report declaration is not an accurate method to determine long-term patients' adherence.³¹

The results of the present study showed that women significantly adhered better to CPAP therapy than men. However, our finding was in contrast with other studies.^{20, 32} While the number of female participants in our study was high (43%), fewer women participated in other studies, which in turn undermined the generalizability of their results. We also found that older patients were more adherent to CPAP therapy. This was in line with the finding of a previous study.²⁰ However, Salepci and colleagues reported a higher level of adherence among younger patients.¹² In terms of BMI, similar to other studies,^{31, 32} we also found no significant difference between the adherent and non-adherent group. Similarly, no significant difference between the type of diagnostic tests (HST versus PSG) was found between the groups.

Despite a considerable effort by numerous researchers to determine factors affecting patient adherence to the CPAP therapy, their findings have been inconsistent and debatable.^{9, 20, 31-33} This is probably due to the diversity of factors that affect the adherence rate (e.g., patient characteristics, titration procedures, device technology, side effects of the therapy, and social/psychological parameters).^{14, 24}

Based on the psychological and behavioral theories, knowledge is a prerequisite for adopting a healthy behavior and a determinant of adherence to a treatment procedure.²⁵

Considering that the adherence rate among our participants decreased over time, it is therefore recommended to design and apply targeted interventions in the early stages of the treatment, based on the behavioral change theory. Recent advances in digital information technology could also be utilized to provide remote education on a regular basis.

The main strengths of the present study were data collection from multiple centers (i.e., the inclusion of different socioeconomic factors) and almost equal inclusion of male and female patients. Additionally, a combined qualitative and quantitative analysis ensured high reliability and generalizability of the findings. The main limitations of the study were inconsistencies in the database from the sales office (different timeframes for using the device) and the failure to save data by some patients. As a result, the number of samples decreased over a long follow-up period. Moreover, unavailability of patients and incomplete medical records from the sleep centers resulted in the exclusion of some patients, which in turn negatively affected the representativeness of the qualitative analysis. Despite our efforts to interview all the excluded patients, only a few agreed to participate.

Considering the limitations of self-report declarations, it is recommended that future studies utilize an objective data collection method to obtain more reliable information. In addition, the differences in diagnostic outcomes from HST and PSG tests³⁴ should also be considered. The use of dedicated analysis for each diagnostic test and the inclusion of a larger sample size are recommended.

Conclusion

A high percentage of OSA patients had poor adherence to CPAP therapy. In addition to demographic and clinical characteristics, device-related issues could also affect patient adherence. Such issues could be adequately resolved by providing complementary information during follow-up care. Moreover, efforts to reduce costs through comprehensive insurance coverage or government subsidy would improve adherence to CPAP therapy. The effect of cultural, economic, and social factors on the adherence rate should also be investigated.

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