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Original Article

Long-term compliance to continuous positive airway pressure therapy in patients with severe sleep apnea syndrome

Şiddetli uyku apne sendromu olan hastalarda sürekli pozitif hava yolu basıncı tedavisine uzun süreli uyum

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ABSTRACT

Background and Aim: Compliance is the adherence of the patient to continuous positive airway pressure (CPAP) therapy after his/her decision to start treatment. The aim of this study is to evaluate the compliance to CPAP therapy in a large patient population and the results were presented after 5 years of follow-up period in order to emphasize long-term compliance with CPAP treatment in the light of the literature.

Materials and Methods: Patients who could not afford CPAP device or attend regular controls were excluded from the study and the remaining 174 patients were included in the study. At the end of 5 years, the patients were called back. A total of 110 patients met the eligibility criteria for the study110 patients (79 males, 31 females) whose charts were reviewed.

Results: Fifty of 110 study participants (45.5%) regularly used CPAP device for ≥4 hours and the remaining 60 (54.5%) patients did not use CPAP device regularly. At the end of 5 years, we found that 36.4% of the patients used the device 4 hours a night. AHI severity does not affect adherence to the device and compliance rates (χ^2=2.743; p=0.254).

Conclusion: The patients compliance rates with CPAP device was found concord with the literature. This study conveys greater importance than other relevant studies in the literature in that it encompasses a larger patient population followed up for a longer period.

Keywords: sleep apnea syndrome, positive airway pressure, compliance

ÖZ

Giriş ve Amaç: Kompliyans, hastanın tedaviye başlama kararından sonra sürekli pozitif havayolu basıncı (CPAP) tedavisine uymasıdır. Bu çalışmanın amacı, geniş bir hasta popülasyonunda CPAP tedavisine uyumu değerlendirmektir ve sonuçlar literatür ışığında CPAP tedavisine uzun vadeli uyumu vurgulamak amacıyla 5 yıllık takip süresinden sonra sunulmuştur.

Gereç ve Yöntem: CPAP cihazı alamayan veya düzenli kontrollere katılamayan hastalar çalışmaya alınmadı ve kalan 174 hasta çalışmaya dahil edildi. 5 yılın sonunda hastalar geri çağrıldı. Toplam 110 hasta, çizelgeleri gözden geçirilmiş 110 hasta (79 erkek, 31 kadın) için uygunluk kriterlerini karşılamıştır.

Bulgular: Çalışmaya katılan 110 kişiden 50'si (%45,5) düzenli olarak ≥4 saat CPAP cihazı kullanmış ve geri kalan 60 (%54,5) hasta düzenli olarak CPAP cihazı kullanmamıştır. 5 yılın sonunda hastaların %36,4'ünün cihazı gece 4 saat kullandığını tespit ettik. AHI şiddeti cihaza uyumu ve uyum oranlarını etkilemez ($\chi 2 = 2,743$; $p = 0,254$).

Sonuç: Hastaların CPAP cihazına uyum oranları literatürle uyumlu bulunmuştur. Bu çalışma, daha uzun süre takip edilen daha geniş bir hasta popülasyonunu kapsaması bakımından literatürdeki diğer ilgili çalışmalardan daha fazla önem taşımaktadır.

Anahtar kelimeler: uyku apne sendromu, pozitif hava yolu basıncı, kompliyans

INTRODUCTION

Obstructive sleep apnea syndrome (OSAS) is an important health problem characterized by cessation of airflow within the upper respiratory tract, oxygen desaturation and interruption of sleep and may be associated with significant morbidity and mortality [1,2]. Continuous Positive Airway Pressure (CPAP) therapy which is based on the principle of maintaining patency of upper respiratory tract by external application of positive pressure on the upper respiratory tract during sleep is a "gold standard" treatment modality for respiratory system disorders occurring during sleep especially in patients with severe OSAS [3,4]. Since CPAP devices show their ameliorating effects only during their application, they haven't any completely curative effect. Therefore, the patient benefits from the treatment as long as he/she uses the device [5]. On this issue according to generally accepted principle, total application time of the device should last more than 70% of the duration of the patient's treatment and at least 4 hours a night [6]. Despite its benefits, compliance to CPAP is at a suboptimal level.

Compliance is the adherence of the patient to CPAP therapy after his/her decision to start treatment [7]. When we review the studies on compliance to CPAP treatment, based on the self-reports of the patients, compliance rates range between 65 and 90%, while control systems have revealed that 29-83 % of the patients are using their CPAP devices [8]. Detection of higher usage rates have been associated with feedback received only from the patients themselves [9]. Very few studies have evaluated long-term CPAP use objectively and still very scarce number of these studies have been performed with more than 50 patients. Only very few of the researchers have followed up their patients for more than one year [10,11].

In this study, compliance to CPAP therapy in our large patient population was evaluated and our results were presented after 5 years of follow-up period in order to emphasize long-term compliance with CPAP treatment in the light of the literature. This study conveys greater importance than other relevant studies in the literature in that it encompasses a larger patient population followed up for a longer period.

PATIENTS AND METHODS

Study design: The study was performed in the Ankara Diskapi Yildirim Beyazit Training and Research Hospital between 2008 and 2017. It is a prospective study. The patients who presented with snoring, excessive daytime sleepiness and apneic symptoms to our outpatient clinic were hospitalized overnight in the sleep laboratory and polysomnographic (PSG) examinations were conducted. Number of apneic, hypopneic episodes per hour was defined as apnea-hypopnea index (AHI). Based on AHI the patients were classified as mild (AHI=5-15), moderate (AHI=15-30) and severe OSAS (AHI>30). CPAP therapy was recommended for patients with moderate OSAS with risk factor(s) or severe OSAS. These patients were hospitalized for one more night and CPAP therapy was titrated. Patients who could not afford CPAP device or attend regular controls

Table 1. Descriptive analyses of the patients included in the study

Variables	*mean±SD (min-max) median (IQR) (min-max)*
Age	47.4±7.3 (28.0- 61.0)
Pressure (mmHg)	9.7±2.5 (5.0-15.1)
Compliance (h/day)	6.0 (2.0) (4.0- 7.0)
Apnea hypopnea index	45.6 (40.0) (12.4-122.3)
Oxygen desaturation index	39.9 (40.1) (1.7-133.4)
T90	30.4 (122.9) (0.0-386.0)
Median O_2 saturation	91.7 (5.1) (60.0-95.9)
Minimum O_2 saturation	77.0 (14.0) (48.0-89.0)
PaO_2	81.0±9.7 (57.5-103.9)
$PaCO_2$	36.0±3.5 (28.9-44.9)
sO_2	95.8 (1.9) (90.5-98.9)

T90 = % sleep time below $Sp0_2$

Table 2. Compliance according to gender

Gender	PAP compliance ≥4 hours	PAP compliance <4 hours	*p* Value	*p* Value
Male (n=79)	37/79	42/79	0.180	0.642
Female (n=31)	13/31	18/31	0.245	

Table 3. Compliance according to apnea hypopnea index

AHI	PAP compliance ≥4 hours	PAP compliance <4 hours	*p* Value	*p* Value
0-30	9 (18%)	19 (31.7%)	0.114	0.254
30-70	28 (56%)	29 (48.3%)	0.245	
>70	13 (26%)	12 (20%)	0.226	

AHI= Apnea hypopnea index

were excluded from the study. At the end of 5 years, the patients were called back. We could get in touch with patients whose phone numbers and/or addresses were unchanged. Stored data of the devices were examined to estimate total and daily compliance rates. Besides, arterial blood gas values of all patients were noted. Ethics committee approval was obtained for the study.

Statistical analysis: Data were analyzed using IBM SPSS Statistics 21.0 (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.). A normal distribution of the univariate data was checked using Shapiro-Wilk test. Parametric tests were applied to data of normal distribution and non-parametric tests were applied to data of questionably normal distribution. Data are expressed as mean±SD or median (interquartile range), as appropriate. All differences associated with a chance probability of .05 or less were considered statistically significant.

RESULTS

Patients who could not afford CPAP device or attend regular controls were excluded from the study and the remaining 174 patients were included in the study. At the end of 5 years, the patients were called back. A total of 110 patients met the eligibility criteria for the study. Of the 110 patients (79 males, 31 females) whose charts were reviewed, the mean was 47.4±7.3 (range, 28 to 61) years. Individual data of the patients were presented in descriptive analyses (**Table 1**). Fifty of 110 study participants (45.5%) regularly used PAP device for ≥4 hours and the remaining 60 (54.5%) patients did not use PAP device regularly.

The patients used various brands of PAP devices (19 patients (38.0%) Goodknight 420E (Puritan Bennett/Tyco Healthcare; Pleasanton, CA), 13 patients (26.0%) Horizon LT plus (DeVilbiss/Sunrise Medical; Carlsbad, CA), six patients (12.0%) AutoTREND (Hoffrichter GmbH; Schwerin, Germany), two patients (4.0%) EvoCPAP (Evo804 comfortPAP, two patients (4.0%) SleepStyle™ 600 series (Fisher & Paykel Healthcare Limited, Auckland, New Zeland), two patients (4.0%) REMstar auto (Respironics; Murrysville, PA), two patients (4.0%) SOMNOsmart 2 (Weinmann GmbH; Hamburg, Germany), one patient (2.0%) Magellan (MAP; Munich, Germany), one patient (2.0%) Medical Industries (Sleepap; America), one patient (2.0%) Moritz BiPAP (ResMed; Germany). Positive airway pressure was delivered using APAP (14/50; 28.0%), BIPAP (4/50; 8.0%), BPAP (12/50;24.0%) and CPAP (20/50; 40.0%) devices. The compliance of CPAP users was 6.0±1.0 hr/d. Compliance with the device did not differ between male and female patients (p=0.642) (**Table 2**).

Besides the patients were divided into three groups according to their AHI values and compliance rates for each group were examined. The patients with AHI values of 0-30, 30-70 and ≥70 constituted Groups 1, 2 and 3, respectively. Accordingly, AHI severity does not affect adherence to the device and compliance rates (χ^2=2.743; p=0.254) (**Table 3**).

DISCUSSION

Compliance with the device used has an important role in the success of PAP therapy. Compliance is defined by the patient's adherence to PAP therapy, after he/she decided to start the therapy. After a night passed in sleep centers on PAP therapy, nearly 70% of the cases accept to continue their treatment at home. However, problems arising within the first week of therapy decrease PAP use and within the first months 10% of the patients discontinue PAP therapy [12]. Studies on compliance have not demonstrated any correlation between compliance and age, gender,

educational level, economical status and personality [13]. In our study, a statistically significant difference was not found between the compliance, gender and age of the patients.

Compliance to PAP therapy is evaluated with the duration of PAP usage. Application period of the PAP device is determined by either asking the patient or looking at the time counters on the monitor of the PAP devices. If only patients self-reports are taken into consideration then compliance rates ranges between 65 and 90 percent [8]. Compliance rates drop to 46 % when counter system is used [8]. Krieger et al. estimated long-term compliance using time counter of the CPAP device and after a nearly 8 month-follow-up period, more than 90 % acceptance rates were reported for 46 patients with OSAS [10]. This phenomenon was taken into account in our study and time counter systems of the devices were checked to obtain data that are more precise.

For a satisfactory compliance, investigators have various criteria. For a successful use of a PAP device, as a consensus, PAP device should be used during 70% of the required time period and at least 4 hours a night. Some investigators have reported that 4 hours of PAP use is required to ensure adequate oxyhemoglobin saturation [7], while others advocated PAP use for 6 nights a week and at least 6 hours a night [12,14,15].

In our study, 50 (45.5%) patients used PAP device and 60 (54.5%) patients did not use this device. At the end of 5 years, we found that 36.4% of the patients used the device 4 hours a night, which is in compliance with the literature. In our study, 20 (40.0%) patients used CPAP, while 30 (60.0%) patients did not use it. Any significant difference (i.e. between AHI values) between the severity of the disease in patients who used or did not use CPAP device was not found, while airway pressures in PAP users were significantly lower than non-users.

In our study, in order to determine if severity of OSAS affected compliance, the patients were divided into three groups according to AHI values and for each group compliance rates for each group were estimated. Accordingly, increased AHI does not affect adherence to the device use and compliance (χ^2=2.743; p=0.254).

In a study performed on 24 patients by Sanders *et al.*, long-term (10±8 months) compliance to CPAP therapy at home was analyzed and long-term compliance rate of 75 % was detected [16]. In a multicentered prospective European study, 75% of the cases were regular CPAP users [15]. According to the definition of regular usage in this study, during the 70% of the first 3 months of the treatment period, the patients used their PAP devices for 4 hours a night. In the same study, compliance rate in the USA was found to be 46 percent. This difference was said to stem probably from cultural diversities or different methods of patients' monitorization. Kribbs *et al.* followed up compliance of 35 patients by tracking monitor displays of CPAP devices. Even though 60 % of the patients reported CPAP use every night, in fact only 16 (46%) patients used CPAP device regularly for at least 4 hours during 70 % of the duration of their monitorization period [17]. Rauscher *et al.*, reported that after the first night on CPAP therapy, 47 of 65 (72%) patients accepted treatment at home. Age, gender, body weight, daytime PaO2 values did not differ between those accepted or rejected CPAP use [18]. However, in the study by Rolfe et al. during 78 months of the follow-up period, long-term CPAP use was reportedly accepted by 64% of the patients. In patients with excessive daytime sleepiness and severe hypoxemia, rate of acceptance is at its highest level. Hypoxemia has been indicated to be the best indicator of acceptance of CPAP [14]. In a study by Hoffstein *et al.* 105 (70.9%) out of 148 patients continued to use PAP device for a mean period of 17±11 months [9]. Majority (81%) of the cases perceived CPAP as an effective treatment and 83% of them reported a subjective improvement. The authors emphasized that compliance was not correlated with severity and side effects of the disease. They also indicated that rather awareness of symptomatic improvement by the patients and their desire to get well would increase compliance.

Hussain, S.F. et al. reported that obesity, excessive daytime sleepiness, witnessed apnea and improvement of daytime symptoms following use of CPAP were predictors of improved compliance. Use of antidepressants and CPAP induced sleep disturbances were predictors of poor compliance.

Lee et al. [20] reported that in southeast Asian population almost half of all patients with significant OSA rejected CPAP treatment upfront, but adherence among those who started CPAP is comparable to other reports. Challenges with CPAP acceptance as well as CPAP adherence need to be addressed to improve outcomes.

When all these studies are reviewed, the most effective factors on compliance to PAP use appear to be symptomatic improvement after CPAP use and excessive daytime sleepiness. The correlation between severity of sleep apnea and compliance is not a stable finding.

CONCLUSION

In this study, compliance with PAP device in our large patient population was evaluated after 5 years of follow-up period in order to emphasize long-term compliance with CPAP treatment. Our study conveys greater importance than other relevant studies in the literature in that it encompasses a larger patient population followed up for a longer period. Feedback provided from the stored data of the device, instead of the patients' self-reports yielded outcomes that are more objective and increased reliability of the study. We think that our study will shed light on future studies investigating the ways of increasing compliance of the OSAS patients to PAP therapy.

DECLARATION OF CONFLICT OF INTEREST

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