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The effects of frequent follow-up on compliance in patients receiving PAP therapy due to OSA

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Abstract. – OBJECTIVE: We planned to investigate the effect of close monitoring on compliance and the factors affecting compliance among patients receiving positive airway pressure (PAP) treatment due to obstructive sleep apnea (OSA).

PATIENTS AND METHODS: This study was a single-center, prospective, randomized, controlled study. Between January 2022 and May 2022, 192 patients who were 18 years of age or older, had been newly diagnosed with OSA, and underwent PAP titration at our sleep laboratory were included in the study.

RESULTS: One hundred twenty-eight patients were randomized as group 1 (study group) and group 2 (control group). There was no correlation between good continuous positive airway pressure (CPAP) compliance and diabetes mellitus, hypertension, hyperthyroidism, or allergic rhinitis. However, there was a statistically significant correlation between good CPAP compliance and chronic obstructive pulmonary disease (COPD) or asthma.

CONCLUSIONS: Sleeping with such a device will be very difficult and uncomfortable. As observed from previous studies, adherence to CPAP is a critical problem worldwide regardless of geography, education, age, and sex. Telemedicine monitoring may be a good follow-up tool. Nevertheless, the essential tool is interpersonal communication by phone calls, face-to-face computer communication, or frequent visits.

Key Words:
OSA, Obstructive sleep apnea, Compliance, PAP.

Introduction

Obstructive sleep apnea (OSA) is a disease characterized by obstructive apnea and hypopnea that develops due to recurrent collapses in the upper airways during sleep. This sleep-related disorder affects millions of people across the world. It is defined as a condition where people experience pauses in their breathing during sleep. These pauses can range in length from milliseconds to minutes, depending on the severity of the apnea. People who struggle with sleep apnea also often experience a decrease in oxygen saturation during sleep, excessive daytime sleepiness, fatigue, and low quality of life. Nighttime desaturations due to hypoxia and the resulting discharge of the adrenal system can lead to hypertension, diabetes mellitus, coronary artery disease, depression, impotence, and other diseases that frequently accompany OSA[1]. The onset of sleep apnea is attributed to several factors, but the most common causes are obesity, large neck circumference, and genetic predisposition. These things can cause the chest muscles and the tongue to relax during sleep and block the air passages, leading to shallow breaths and eventually snoring. People with sleep apnea are at risk for various health issues, including high blood pressure and stroke. People with this condition are also likely to experience poor quality of sleep, which can lead to fatigue, moodiness, and general feelings of unwell-being. In addition, those with sleep apnea are at an increased risk of developing depression and anxiety.

There are a variety of options available to treat sleep apnea. For example, lifestyle modifications such as losing weight and sleeping on one's side may help to reduce the severity of sleep apnea. However, these are easy to say but hard to do advice. Continuous positive airway pressure (CPAP) machines are often prescribed to those with sleep apnea. CPAP supplies air into the airways through a mask worn over the mouth. This helps to prevent the airways from collapsing and allows for easier breathing. The device is worn while sleeping and utilizes air pressure to keep the air passages open and stop them from collapsing while sleeping. The CPAP machine

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comprises a mask worn over the face, a tube, a motor, and a battery, with the motor responsible for pushing air into the tube. When the wearer exhales, the pressure in the tube decreases, and the motor increases pressure. This pressure helps the airways stay open and becomes constricted when the pressure is too low. The pressure is set to what is deemed as a comfortable level for the wearer. The mask should fit snugly but not tightly, allowing for comfortable breathing[2,3].

Despite the effectiveness of PAP treatment, patient compliance with treatment is often inadequate. There needs to be a clear definition of treatment compliance in PAP treatment. However, in literature and clinical practice, compliance is considered at least 4 hours of PAP use per night for at least 70% of the treatment period[4]. Noncompliance is often detected during the first two weeks of treatment and continues in the long term[5,6]. Different methods are being tried to ensure the first adaptation of the patients in this situation to device usage. As in many other fields, if patient-physician communication is good in these patients, problems may be solved easier. It may be beneficial for those patients to come together with their doctors frequently or communicate by phone or online communication systems like Zoom.

In our study, we planned to investigate the effect of close monitoring on compliance and the factors affecting compliance among patients receiving positive airway pressure (PAP) treatment due to OSA.

Patients and Methods

This study was a single-center, prospective, randomized, controlled study approved by the hospital's ethics committee. Informed consent forms were obtained from all participating patients.

Study Group

Between January 2022 and May 2022, 192 patients who were 18 years of age or older, had been newly diagnosed with OSA, and underwent PAP titration at our sleep laboratory were included in the study. Of these patients, 64 were excluded from the study because they did not obtain and bring the device. The remaining patients who agreed to participate in the study were randomly divided into two groups. Both groups were given introductory training with the devices. The first group was called by phone on the 15th day to ask if there were any complaints or problems with the device. Sequentially, they were called for controls at the end of the first, third, and sixth months.

The second group was accepted as the control group, following our clinic's standard procedure in the first and sixth months. The patients who came to the control were asked if there were any problems with the device and any difficulties in use, and they were again informed about the devices and masks.

The steps of the inclusion of the study and control groups are shown in Figure 1.

Good PAP Compliance

When both groups of patients came to control, the nightly PAP device usage hours were objectively calculated by recording the usage time on the device. Good PAP compliance was defined as at least 70% of the night, at least four hours, equivalent to 2.8 hours per night[4].

Short-term compliance was measured during the first follow-up, and long-term compliance was measured during the last follow-up.

The patient's age, weight, height, and other illnesses were obtained from their medical records. Body mass index was calculated by dividing weight by height in meters. Education level was recorded as elementary school, high school, and university.

Standard All-Night PSG

All patients underwent standard all-night polysomnography (PSG) (CometGrass; Astro-Med, Inc., West Warwick, RI, USA).

The PSG recordings included three-channel electroencephalography, two-channel electrooculography, one-channel submental electromyography, oxygen saturation using an oximeter probe, respiratory movements using chest and abdomen belts, nose pressure using a pressure sensor, thermistor, electrocardiography, and leg movements using tibial surface electrodes.

According to the American Academy of Sleep Medicine (AASM) criteria[7,8], sleep stages and respiratory parameters were scored. Apnea was defined as a reduction in airflow of at least 90% for at least 10 seconds, and hypopnea was defined as a reduction in airflow of at least 30% accompanied by at least a 3% desaturation in the preceding 30 seconds, and a reduction in chest wall movement and/or arousal. Apnea hypopnea index (AHI) denoted the average number of apneas and hypopneas per hour of sleep. OSA was defined

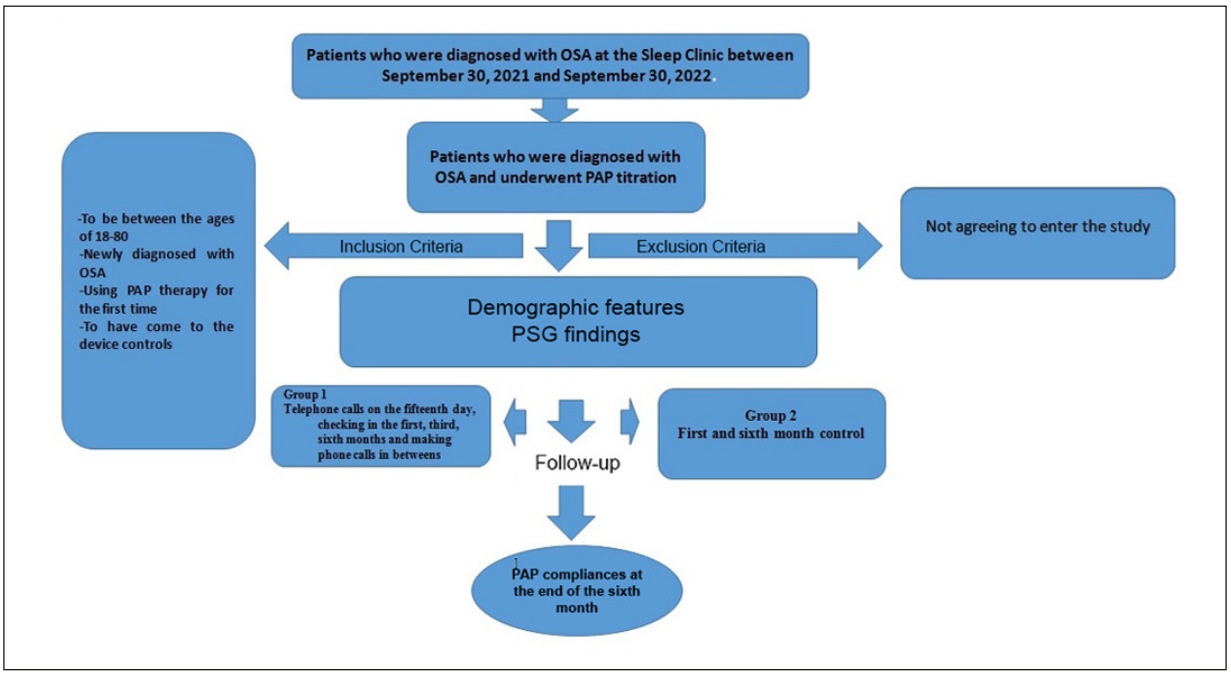

Figure 1. Consort flow diagram of patients through the study.

as an AHI of at least five events/hour[9,10], and the degree of OSA was graded as mild (AHI 5.0-14.9 events/hour), moderate (AHI 15.0-29.9 events/hour), or severe (AHI >30.0 events/hour). After the diagnostic night, a second full-night PSG with nasal PAP was performed.

Titration of the device by qualified sleep specialists following AASM standards is essential for the long-term use of CPAP[10]. The strain was set at the minimum required to eliminate snoring, obstructive events, and arousals and to improve oxygenation. Nose or oronasal masks were worn for titration.

The patients were provided with suitable PAP gadgets according to the normal process of our clinic. In situations with supine and REM-dependent OSA, auto-titrating PAP (APAP) was administered, and in cases of patients requiring high pressure (12 bar), a bilevel PAP (BPAP) device was administered. The S9 series (ResMed, San Diego, CA, USA) was used for long-term CPAP titration and usage, whereas the VPAP IV (ResMed, San Diego, CA, USA) was used for BPAP titration and prolonged usage.

Statistical Analysis

The obtained data were analyzed using the SPSS 22.00 (IBM Corp., Armonk, NY, USA) for the Windows package program. Percentage distribution, mean, standard deviation, and median values were given in descriptive statistics. The Chi-square test was used to determine the difference between categorical variables, parametric tests (*t*-test, One-Way ANOVA) were used for those with normal distribution, and nonparametric tests (Mann-Whitney U, Kruskal-Wallis' test) were used for those who did not. The parametric test (*t*-test independent samples) was used to determine the differences between the mean of the related groups, and the nonparametric test (Wilcoxon-Rank test) was used in those who did not. Evaluating the statistical results, a p-value <0.05 was considered significant.

Results

The study was initiated with 192 patients. Of these patients, 64 were excluded from the study because they did not obtain and bring the device. One hundred twenty-eight patients were randomized to Group 1 (the study group) and Group 2 (the control group). The details are shown in Table I and II. There were 52 males, and 14 females in the study group, whereas 49 males and 13 females were in the control group. The average age

Table I. Demographic and characteristics of study patients at baseline.

	Mean value of study group	Mean value of control group	*p*-value
Age	49.5	49.5	$p > 0.05$ ns
Sex	52 M-14 F	49 M-13 F	$p > 0.05$ ns
BMI	31.54	33.15	$p > 0.05$ ns
Smoking (0: No, 1: Up to 15 per day, 2: More than 15 per day)	36/66	44/62	$p < 0.05$
Education (1: Elementary, 2: High School, 3: University)	2.05	1.74	$p > 0.05$ ns

Table II. Details of study and control group cases.

	Study group (n = 66)	Control group (n = 62)
AHI, events/hours	37.22	45.08
ESS score	8.12	8.85
Pulmonary disease, %	5	4
Hypertension, %	27	25
Diabetes mellitus, %	16	13
Cardiac disease, %	6.3	3.8

Values are mean (standard deviation) or percent patients. AHI: apnea hypopnea index; ESS: Epworth Sleepiness Scale.

of both groups was 49.5. The body mass index of the study group was 31.54, and 33.15 in the control group. The AHI and Epworth Sleepiness Scale (ESS) scores of both groups were close to each other. The ratio of associated diseases such as pulmonary disease, hypertension, diabetes mellitus, and cardiac disease was similar in both groups.

Good PAP compliance and correlation between each parameter checked were listed in Table III. Although we did not pay attention, the mean age in both groups was the same.

There was no correlation between good CPAP compliance and diabetes mellitus, hypertension, hyperthyroidism, or allergic rhinitis. However, there was a statistically significant correlation between good CPAP compliance and chronic obstructive pulmonary disease (COPD) or asthma.

Discussion

Patients who encounter the suggestion of using a PAP device for the first time may also hesitate whether to use this device or not. This hesitation has two components. The first is the mechanical discomfort of the device's mask during sleep. It is easier to overcome this ailment because patients can overcome this problem by trying and determining the appropriate lying position. For those who cannot start continuous usage identifying patients with this condition through early interviews and trying different masks can yield valuable results. The second and more critical problem is the psychological effect of PAP. The idea of sleeping connected to a device can make individuals uncomfortable. Moreover, this device will undoubtedly disrupt or negatively affect sexual life. Even if there is no such effect, the uneasiness or suspicion bothers predominantly middle-aged people. Continuous follow-up is beneficial in frequent speaking, morale, and motivation. The positive effect of this situation has been shown in the results of our study[11,12]. It is observed that patients first start using the device when they are alone at home and then wear the device when they sleep with their spouses. Some patients who refused at first, start using it after getting used to sleeping with their devices on, even if they go for half an hour's nap. This may be shown as an indicator of how much they benefit from the device.

Table III. Follow-up details of study and control group cases.

	Mean value of study group	Mean value of control group	*p*-value
30th day CPAP Usage per night (h per night)	5.92	4.87	$p < 0.001$
90th day CPAP Usage per night (h per night)	6.04	5.14	$p < 0.001$
180th day CPAP Usage per night (h per night)	8.1	6.64	$p < 0.001$

Using CPAP telemonitoring with automated feedback messaging improved 90-day adherence in patients with OSA. Telemedicine-based education did not significantly improve CPAP adherence but did increase clinic attendance for OSA evaluation. Similarly, our patients showed higher adherence to telephone calls.

Patients with OSA were monitored using a CPAP machine connected to a modem in research by Fox et al[14]. Per the established norm, all patients were given CPAP instructions, a mask, and an automatic titrating machine. A modem was added to the PAP machine (EncoreAnywhere®, Philips Respironics Inc., Pittsburgh, PA, USA), and patients were instructed in their use by a research coordinator. The physiological information was collected daily. The modem was programmed to send it to an online database *via* telephone (PAP adherence, applied PAP pressure, mask leak, and residual respiratory events). After two days, the research coordinator called participants to check in on their progress, make sure they were using the equipment correctly, and address any problems that had arisen. On weekdays (excluding holidays), the research coordinator at UBC would review the downloaded data and get in touch with the patient if any of the following occurred: mask leak >40 L/min for more than 30% of the night; 4 hours of use for two consecutive nights; machine-measured AHI >10 events/hr; 90th percentile of pressure >16 cm H_2O. The research coordinator called the patient, who asked how they were doing overall and whether they were experiencing any problems (such as dry mouth, mask troubles, or device pain). It was recommended by the study coordinator that patients use PAP if a lack of motivation was the sole barrier. Suppose the patient's responses and the physiologic data indicate that the patient might benefit from speaking with or seeing the PAP coordinator. In that case, the research coordinator will discuss the case with the PAP coordinator (the same person who assisted with the patient's care in the standard arm). Finally, we would go over the exact methods we use in our clinic to boost patient compliance (e.g., a new mask, chin strap, alterations of pressure settings, modifications of humidifier settings, saline nasal sprays). Patients saw their primary care doctor again after 4 to 6 weeks of therapy, at which point their medical records were reviewed (including CPAP pressure, mask leak, residual respiratory events, and compliance). We also spoke about any problems that had come up throughout treatment[13,14]. Sleep specialists reviewed the data collected by modern means after three months of treatment with the patient. ESS ratings on completed questionnaires were comparable to those in the normative group. One possible interpretation of these results is that data control is crucial but does not enhance adherence[13,14]. This information might be used as a form of telemedicine monitoring, providing a valuable means of following up on patients' data in a way that does not compromise their privacy or adherence to treatment plans.

According to Sarac et al[15], educating patients by showing them their PSG charts on the diagnostic and PAP titration evenings and checking in with them frequently significantly increased the likelihood of sticking with the therapy over the long run. Secondary school education negatively correlated with PAP adherence, while obesity and baseline OSA severity were also significant predictors.

Based on these results, Turkey must adopt the most up-to-date standards for managing OSA patients using home-monitoring devices to alleviate the current clinical burden. This would allow physicians to implement educational support measures, which are especially important for patients with little literacy. The healthcare economy may be significantly affected by these measures[15]. Our study may be accepted as the continuation of this conclusion.

Limitations

The limitation of our study is the comparison of each follow-up tool. The next step may be the comparison of the efficacy of these tools, such as phone calls, face-to-face computer communication, *vs.* frequent visits.

Conclusions

Sleeping with such a device will be very difficult and uncomfortable. As observed from previous studies, adherence to CPAP is a critical problem worldwide regardless of geography, education, age, and sex. Telemedicine monitoring may be a good follow-up tool. Nevertheless, the essential tool is interpersonal communication by phone calls, face-to-face computer communication, or frequent visits.

Conflict of Interest
The Authors declare that they have no conflict of interests.

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Ethics Approval
Ethics approval was obtained from University of Health Sciences, Sureyyapasa Chest Diseases and Thoracic Surgery Training and Research Hospital, (#09.12.2021/116).

Clinical Registration Number
The study was registered on clinicaltrials.org with the number: NCT05894733.

Informed Consent
Informed consent forms were obtained from all participating patients.

Authors' Contribution
Makbule Ozlem Akbay: Planning, designing, literature survey, statistical analysis, interpretation of the results, writing, submission. Sema Saraç: Planning, designing, data collection, literature survey.

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