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Positive Airway Pressure Adherence of Obstructive Sleep Apnea Patients

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I have no conflict of interest with any PAP device company.

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ABSTRACT

Introduction:PAP(Positive Airway Pressure) is the gold standard treatment for OSAS(Obstructive Sleep Apnea Syndrome).But it is not well tolerated and requires long term follow-up.

Objectives: We aimed to assess prospectively subjective and objective adherences and factors that effect adherence in OSAS patients who were in the course of PAP treatment.

Methods: Patients using PAP were questioned for adverse effects of treatment and were assessed with ESS (Epworth Sleepiness Scale) at 1st, 3rd, 6th, 12th months and once in every six months after first year. PAP usage, objective and subjective adherence were assessed. Patients who used PAP for at least 4 hours per night for at least 70% of the days monitored were regarded as adherent and who didn't meet this criteria were considered as non-adherent. The relationship between adherence and demographic data, PSG (polysomnography) findings, ESS(Epworth Sleepiness Scale) scores and adverse effects were statistically analyzed.For statistical analysis; Chi-square test,Kolmogorov-Smirnov test,T-test,Mann Whitney-U test and Logistic Regression analysis were used with SPSS package program.

Results: Six hundred and forty eight patients who were diagnosed with OSAS by PSG and accepted to use PAP in our sleep center between January 2005-June 2011 were included. Four hundred and fifty one patients(69.6%) were men and 197(30.4%) were women.Two hundred and forty eight(38.3%) of cases attended follow-ups, 246(37.9%) were called by phone and 154(23.8%) couldn't be reached. Of the whole population 63.9% had obtained their PAP machine. In 248 cases who attended to follow-ups subjective adherence was 85.1% and objective adherence was 64.5%.Improvement in ESS score and satisfactory sleep were found to be significantly higher in adherent group($p<0.05$).Chest discomfort, difficulty falling asleep and sleep disturbances were significantly higher in the nonadherent group($p<0.05$).

Conclusions: Of the whole population, just 38.3% has attended follow-ups. The objective adherence is lower than subjective adherence in patients who attended to follow-ups. Additionally, younger patients were found to be more adherent and the most important factors that correlate with adherence were observed to be significant improvement of day time sleepiness and effect of treatment on satisfactory sleep. It was concluded that PAP recommended patients should necessarily be followed up and during follow-ups; machine times on counters should be controlled.

Key Words: Obstructive sleep apnea, subjective and objective CPAP adherence, Epworth Sleepiness Scale.

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INTRODUCTION

OSAS (Obstructive Sleep Apnea Syndrome) is thought to be present in 2% of female and 4% of male adults. Its prevalence even exceeds 8% in men aged 40-59. In some studies[1-3] it was reported that prevalence was around 20% in men in this age group and as high as men in post-menopausal women. For OSAS with hypertension, day time sleepiness, impairment of cognitive functions, ischemic heart disease and stroke; the gold standard treatment is CPAP (continuous positive airway pressure) which was first introduced by Sullivan.[4,5] CPAP increases quality of life by eliminating day time sleepiness and also decreases morbidity and mortality rates related to cardiovascular diseases [6,7].

Efficient CPAP treatment can be accomplished by requires regular usage of the patients. Efficient CPAP usage is named as "adherence". CPAP adherence and factors that affect adherence have become an issue of interest for researchers. In general, CPAP adherence is not associated with age, sex, educational level, economic status, personality or with the characteristics of the disease, including diagnosis or severity or frequency of symptoms.[5,8] The most important factors that decrease CPAP adherence are skin abrasions and ulcerations caused by mask, persistent air leakage, claustrophobia, nasal congestion and exhalation difficulties[5,9]. To increase the adherence, machines may be provided free of cost as administered in our country. In addition; usage of CPAP units with more advanced technology such as an integrated ramp feature, choosing the most comfortable mask and close follow-ups of the patient are factors that increase adherence[5,10]. CPAP adherence is assessed according to duration of usage and there is not a specified standard duration. The adherence is defined as "The percentage of patients who used CPAP ≥4hrs /night (equal to or greater than 4 hours per night) for at least 70% of the days monitored" by Kribbs[11,12]. In some following studies, the term compliance replaced adherence. In several studies it was observed that usages over 6 hours per night were associated with more significant improvement in memory performance and day time sleepiness.[13,14] In Kribbs' study which is considered to be one of the best studies conducted on this subject, when results were assessed according to patients' self-reports; percentage of adherence (subjective adherence), was found to be 60%; when machine times on counters were noted (objective adherence), it was found to be dropped to 46%.[11]

In our study we aimed to assess PAP usage, subjective and objective PAP (positive airway pressure) adherences and factors that affect objective adherence in OSAS patients who are in the course of PAP treatment.

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MATERIALS AND METHODS

Patients:

Six hundred and forty eight patients who were diagnosed OSAS by PSG and accepted to use PAP treatment in our sleep center between January 2005 and June 2011 were included in the study. The polysomnographic data of the first night and titration night were retrospectively analysed, whereas follow-ups were recorded prospectively. Patients whose PAP titrations were unsuccessful and denied a second titration were excluded out of the study. Patients whose PAP titrations were successful but denied PAP treatment due to machine cost or mask discomfort from the beginning were also excluded.

Polysomnography:

Informed consents were taken and first night PSG was conducted. Standard overnight polysomnography included recordings of EEG, electrooculogram, submental and bilateral leg electromyograms and ECG. Air flow was measured by a nasal pressure transducer and respiratory effort by thoracoabdominal piezoelectric belts. Measurement of arterial oxyhaemoglobin saturation was performed by a finger pulse oxymeter. All signals were collected (Viasys Sleep Screen Germany, Viasys CephaloPro Germany, Comet USA) and digitalized (Matrix Sleep, SomnoStar, Grass) on a computerized PSG system conducted by experienced technicians. Sleep stages were scored in 30 seconds epochs using Rechtachaffen-Kales[16] and AASM (American Academy of Sleep Medicine) 2007[17] scoring systems. Each epoch was analyzed for the number of apneas and hypopneas. Apnea was defined a cessation of airflow for >10 seconds, and hypopnea as a reduction of airflow ≥50% for >10 seconds plus an oxygen desaturation of >3% or an arousal.[17,18] Scorings were made by certificated specialists who were experienced in sleep medicine. Disease classification was made according to AASM 2005 Guide.[19] Cases were graded according to AASM 1999[18] criteria as following: AHI (Apnea Hypopnea Index)=5-15 as mild, AHI=15-30 as moderate and AHI>30 as severe. All the cases who had AHI>30 or the cases who had AHI=5-30 with risk factors (hypertension, ischemic heart disease, stroke etc.) or day time sleepiness were recommended PAP titration.[5] After patients' informed consents were taken; CPAP titration was performed automatically with the AutoSet auto-titrating device (ResMed, Australia) with full night polysomnography, according to suggestions by AASM guidelines.[20,21] BIPAP titration was performed by ResMed VPAP IV device in patients who couldn't tolerate high pressures during CPAP titration; patients who have overlap syndrome and nocturnal hypoventilation. The PAP pressure for each patient was set at the minimum pressure needed to abolish snoring, obstructive respiratory events, arousal frequency and improve oxygenation. During the procedures nasal and oro-nasal masks were used.

Procedures:

The cases were admitted to social security institution to obtain their CPAP, BIPAP machines, with prepared

reports and prescriptions according to the pressure levels observed at titration night. Patients were trained on PAP usage by technicians. All the patients who accepted to use PAP were set up appointments for follow-up at 1st, 3rd, 6th, 12th months and once in six months after first year. During follow-up visits; their ESS scores, concomitant diseases (hypertension obesity hypoventilation, COPD, cardiovascular diseases, hypothyroidism, diabetes mellitus, depression) and previous ENT operations (tonsillectomy, nasal septoplasty, uvulupalatopharyngoplasty, nasal polypectomy, radiofrequency ablation) were assessed and they were questioned about quality of sleep (difficulty in falling asleep, sleep disturbances, snoring, noise of the machine , chest discomfort), morning symptoms (dry mouth or nose, headache, waking up tired) and mask related symptoms (skin abrasions and ulcerations, persistent air leakage). Mask type (nasal or oro-nasal) and presence of built-in heated humidifier were noted. Machine time on counter (objective adherence) was compared with patients' self-reports (subjective adherence) of PAP usage in terms of hours per night and nights per week of usage. PAP usage was calculated as total hours of PAP used / number of days passed since the beginning of PAP treatment. For adherence; the definition of "The percentage of patients who used CPAP equal to or greater than 4 hours per night for at least 70% of the days monitored"[11] was used. A telephone call were made with patients who didn't attend follow-ups and were asked whether they have obtained their machines; if they have, whether they have been using it.

Statistical Analysis:

The data were entered into SPSS and analyzed for frequency distributions. Chi-square test was used in the analysis of categorical variables. Kolmogorov-Smirnov test was used to test normality of numerical variables. For normally distributed variables, independent-samples t-test was performed. For those not distributed normally, Mann-Whitney U test was used. Statistical significance level was taken as $p<0.05$. Logistic regression analysis was used for detection of the most important factor affecting PAP usage. Ethical committee approvel was obtained.

RESULTS

In our sleep center 903 patients were admitted for PAP titration and prescribed the machine; 255 of these denied to use the machine. The reasons for denial were the cost the machine for 90 cases and mask discomfort for 165 cases. Our study population consisted of 648 patients who accepted to use PAP; 451 (69.6%) were male, 197 (30.4%) were female. The mean age was 51.2 ± 9.9 and mean BMI (body mass index) was 33.5 ± 6.5. In the first night PSG; the mean AHI was 54.1 ± 26.4; AI (apnea index) was 31.4 ± 26.9; ODI (oxygen desaturation index) was 47 ± 2.9; minSpO2 % (minimum oxygen saturation) was 72.2 ± 13.5. Two hundred forty eight (38.3%) of 648 patients attended follow-ups. A telephone call was made with 400 (61.7%) patients who didn't attend to follow-ups. Two hundred forty six (37.9%) could be reached. One hundred sixty six (25.6%) expressed that they have obtained the machine and have been using it, 80 (12.4%) expressed that they either have not obtained the machine or have not been using it. One hundred fifty four (23.7%) couldn't be reached. In our study cases, PAP usage was found to be 63.9% (a total of 414; 248 determined by follow-up visits, 166 by phone call) (Figure 1).

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The analysis for adherence was performed for 248 patients who attended follow-up visits and the population was divided into adherent and non-adherent groups according to their duration of usage. The subjective adherence was found to be 85.1% and objective adherence was 64.5%. In 23.4% of these cases, self-reports were essentially equal with machine time on counters (i.e. +/-15 minutes per night) ; 30.6% used it for more than 6 hours per night. The mean duration of PAP usage was 16.5 ± 16.8 months. For adherent and non-adherent groups the mean duration of PAP usage in terms of hours per night / nights per week, respectively; 5.7 ± 1.2 h / 7 n and 3.2 ± 1.3 h / 5.1 ± 1.8 n, respectively. Gender and BMI were not significantly different between groups ($p>0.05$). The adherent cases were significantly younger ($p<0.05$). ESS score was found to decrease with PAP usage in both groups, however, this decrease was significantly higher in adherent group ($p<0.001$) (Table 1).

When groups were compared according to their first night and titration night PSG findings; no significant difference was found between groups in terms of PSG findings, machine modes and PAP pressure levels ($p>0.05$) (Table 2). No significant difference was found between groups in terms of presence of concomitant diseases (hypertension, obesity hypoventilation, COPD, cardiovascular diseases, hypothyroidism, diabetes mellitus, depression) and previous ENT operations (tonsillectomy, nasal septoplasty, uvulupalatopharyngoplasty, nasal polypectomy, radiofrequency ablation) ($p>0.05$). The machine modes (BIPAP or CPAP), mask type (nasal or oronasal) and presence of built-in heated humidifier were not significantly different between groups ($p>0.05$).

The presence of adverse effects related to mask (air leakage, skin abrasions and ulcerations), teeth and jaw ache and morning headache were not significantly different between groups ($p>0.05$). Presence of rhinitis symptoms was higher in nonadherent group compared to the adherent group (67.4% and 47.4%, respectively) but the difference was not statistically significant ($p=0.077$). Dry mouth and nose was observed in 62.5% of the adherent group and 70% of the non-adherent group ($p=0.225$). The presence of chest discomfort, sleep disturbances and difficulty in falling asleep were significantly higher in the nonadherent group ($p<0.05$) (Table 3).

The patients were also questioned about whether they had satisfactory sleep or not after they started to use PAP; 91.9% of adherent and 72.6% of nonadherent group expressed that they did. The difference was statistically significant ($p<0.001$).

Multivariate logistic regression analysis revealed that the differences with respect to chest discomfort, ESS and difficulty in falling asleep were of statistical significance whereas no significant relationship was detected for rhinitis symptoms (p values are 0.009, 0.000, 0.001 and 0.608, respectively)

DISCUSSION

Our results show that of 903 patients referred for a sleep study, only 248 continue to follow up for treatment and are adherent to CPAP. At best, including subjects reached only by telephone, 248+166 = 414/908 use CPAP after a PSG diagnosis of OSA is made. The primary endpoint of our study is the low percentage of (38.3%) the cases who came for follow up. The patients who were prescribed PAP machines were asked to come visits after one month and those who did not attend follow-ups were called; however just 38.3% of the cases came for controls. The low ratio of the patients who attended follow-ups may be due to low social and economical status

of the patients and the fact that they did not care about their diseases. It is probable that our cases belong to a different population compared to the previous studies. One of the important reasons for not using the machine is the need to pay some amount of money due to some ensurance problems. One other reason could be the fact that sleeping bound to a machine seems bothering and discomfortable for a vast majority of the cases. Another major finding of the study is that objective adherence is much lower than subjective adherence. The adherent cases were younger. Improving of ESS and having satisfactory sleep are correlated significantly with adherence. Chest discomfort, difficulty falling asleep and sleep disturbances were significantly higher in non-adherent cases.

In the absence of a standardized scale for adherence Kribbs' definition of "The percentage of patients who used CPAP equal to or greater than 4 hours per night for at least 70% of the days monitored" has been used in many studies[11,12,22] which is also the case in our study. In Kribbs' study, subjective adherence was found to be 60% according to patients' self-reports; when microprocessors built-in the machines were controlled, objective adherence was observed to be 46%. In addition to studies conducted to assess solely objective compliance or subjective compliance[22]; there are studies conducted to compare subjective and objective compliances. In these studies; subjective compliance was reported to be higher[23] as in Kribbs' study or subjective and objective compliances were similar.[24] In our study; all the patients who accepted PAP treatment were not adherent. Of the follow-up patients 23.4% have been using PAP as they reported. When the patients who attended follow-ups were considered, adherence which was found to be 85.1% according to patients' self-reports; decreased to 64.5% when machine times on counters were controlled. In our study, adherence due to duration of usage was detected in cases who attended follow-ups, therefore considering the whole group, 38.3% of the cases were followed and objective adherence was calculated for this small group of patients. This may be considered as the limitation of our study. Although Kribbs' criteria were used in many studies to define compliance; in recent studies, it was reported that CPAP usage over 6 hours more significantly improved memory performance and day time sleepiness. In these studies; usage of CPAP over 6 hours was found to be 45.1%[13]and 32.7%[14]. Similarly in our study this value was found to be 30.6% for those who were followed up.

In the study of Sin et al,[25] compliance was reported to be higher in older patients and women. In our study the adherent cases were significantly younger than non-adherent patients. This might be due to the fact that young patients take their diseases more seriously and realize the positive changes in their daily life, including work performances. Gender and BMI were not significantly different between adherent and non-adherent cases. It was found that concomitant diseases and previous ENT operations did not affect adherence.

In Drake's study,[24] the most important factor that affected compliance was found to be an increase in sleep efficiency in titration night PSG compared to first night PSG. In most studies,[26-29] AHI values observed in first night PSG were found significantly higher for patients who have been using PAP and it was interpreted that CPAP compliance was closely related to disease severity. On the other hand, there are also studies[30-32] demonstrating no correlation between CPAP compliance and AHI. In our study; no difference was found between adherent and nonadherent cases in terms of PSG findings; it was interpreted that disease severity didn't affect adherence.

In PAP compliance studies[33-35] machine modes were thought to affect compliance. We found that the percentage

of patients using BIPAP was similar between adherent and non-adherent groups (15% and 16 %, respectively). It was interpreted that machine modes did not affect adherence. In Kribbs' study[11] in which CPAP pressure levels were compared; it was reported that pressure levels did not affect compliance. In our study, mean PAP pressure levels were similar in both of groups and it was found that PAP pressure levels didn't affect adherence. It is known that during PAP treatment, nasal masks are better tolerated. In Mortimore's study[36], compliance was found to be higher in patients using nasal masks but in other studies[37] including ours, it was found that mask type did not affect adherence.

Various results were reported in studies about the effect of the presence of heated humidifiers in machines to compliance. While in some studies the presence of heated humidifiers was reported to increase compliance; in other studies it didn't affect compliance. In all studies, the presence of heated humidifiers was found to increase patient comfort.[22] In Mador's study,[38] it was reported that the presence of heated humidifiers did not increase compliance but decreased adverse-effects of CPAP such as dry mouth or nose. We found that the presence of heated humidifiers did not affect adherence.

In most of the studies, amelioration of day time sleepiness and progression of quality of life were considered when assessing compliance. Although in a few of the studies it was reported that ESS didn't have any relation with compliance; in most of the studies a significant reduction in ESS scores with the usage of CPAP was observed and it was reported that the most important factor that increased compliance was amelioration of day time sleepiness[22,23-25]. In our study as well; initially no difference in terms of ESS scores was found between adherent and non-adherent patients. After PAP usage though, 77.5% of adherent patients' ESS scores were reduced. This reduction was significantly higher compared to non-adherent patients. In addition, adherent patients stated waking up significantly rested compared to non-adherent patients.

In the course of PAP treatment adverse-effects affect compliance significantly. These adverse effects include chest discomfort; anxiety; difficulty in falling asleep; sleep disturbances; air leakage, skin abrasions and ulcerations related to mask usage; dry mouth and nose, rhinitis, rhinorhea, sinusitis, headaches, pressure intolerance, teeth and jaw ache related to pressure and noise or smell related to machine.[22] In our study, dry mouth and nose were found to be high in both of groups. It was previously stated that skin and mask problems are most important factors that affect compliance[5,9] . However, this was not the case in our study. One possible explanation for this could be the fact that patients having problems with mask or skin abrasions did not attend the follow-ups. Chest discomfort, difficulty in falling asleep and sleep disturbances were significantly higher in non-adherent group. A large survey on management of obstructive sleep apnea demonstrated that nasal congestion increased the likelihood for discontinuation of PAP therapy , whereas medications for nasal congestion improved adherence to the treatment.[39] In our study the symptoms of rhinitis were also higher in non-adherent group but the difference wasn't significant. The patients with nasal symptoms were prescribed nasal steroids and we consider this has contributed to adherence.

In conclusion; despite the fact that they were called many times, the cases who attended follow-ups was just

38.3% . The low socio-economical status of our population and unawareness of the seriousness of the disease might contribute to this fact. We conclude that when PAP treatment is prescribed, instructive visual materials should be used. Another important conclusion is that in follow-up patients; objective adherence was lower than subjective adherence. It was found that few percent of the patients have been using PAP as much as they stated in their self-reports. Additionally, younger patients were found to be more adherent and the most important factors that correlate with adherence were observed to be significant improvement of day time sleepiness and effect of treatment on satisfactory sleep. In non-adherent cases; the most important adverse effects were found to be chest discomfort, difficulty falling asleep and sleep disturbances. It was concluded that patients must be made to attend to follow-ups and objective adherence must be assessed during follow-ups. It should be emphasized that sleep quality and daytime hypersomnolence will improve by PAP usage.

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ABBREVIATIONS

AASM: American Academy of Sleep Medicine

AHI: Apnea-Hypopnea Index

AI: Apnea Index

BIPAP: Bilevel Positive Airway Pressure

CPAP: Continue Positive Airway Pressure

ENT: Ear-nose-throat

ESS: Epworth Sleepines Scale

MinSpO2: Minimum Oxygen Saturation

ODI: Oxygen Desaturation Index

OSAS: Obstructive Sleep Apnea Syndrome

PAP: Positive airway pressure

PLMI: Periodic Limb Movement Index

PSG: Polysomnography

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Table 1: Demographical statistics and ESS scores of adherent and non-adherent cases.

	Adherent cases	**Non-adherent cases**	**p value**
	(n = 160)	**(n = 88)**	
Mean age	50.4 ± 10.6	53.3 ± 9.6	**0.035**
Gender			
Men	114 (%71.2)	56 (%63.6)	0.217
Women	46 (%28.8)	25 (%36.4)	
BMI	33.4 ± 6.6	33.6 ± 7.1	0.845
ESS before PAP usage	10.3 ± 5.8	10.9 ± 5.9	0.453
ESS after PAP usage	2.3 ± 2.8	4.6 ± 4.9	**<0.001**
Percentage of patients with a decreased ESS score %	77.5	58	**<0.001**

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Table 2: First night and titration night PSG findings, machine modes and pressure levels of adherent and nonadherent cases.

	Adherent cases	**Non-adherent cases**	**p value**
	(n = 160)	**(n = 88)**	
1st PSG AHI	54.1 ± 26.6	49.9 ± 27.8	0.146
1st PSG ODI	46.6 ± 28.4	42.8 ± 25.9	0.373
1st PSG min SO2%	71.7 ± 13.5	73.7 ± 12.8	0.238
1st PSG PLMI	20.2 ± 24.7	22.8 ± 24.2	0.325
1st PSG sleep efficiency	79.6 ± 11.9	79.3 ± 12.3	0.904
1st PSG letency to sleep	20 ± 28.1	16.4 ± 14.9	0.674
1st PSG latency to REM	155.5 ± 85.9	150.9 ± 100.9	0.211
PAP PSG AHI	5.6 ± 5	5.2 ± 5.1	0.266
PAP PSG ODI	4 ± 5.2	4.3 ± 5.9	0.932
PAP PSG min SO2%	87.9 ± 6.8	86.7 ± 8.1	0.207
PAP PSG PLMI	8 ± 11.3	11.5 ± 15.3	0.122
PAP PSG sleep efficiency	75.9 ± 12.4	77.3 ± 12.4	0.373
PAP PSG latency to sleep	24 ± 23.3	21.5 ± 16.2	0.763
PAP PSG latency to REM	131.7 ± 95.2	128.7 ± 79.5	0.867
CPAP mode %	85	84	0.849
BIPAP mode %	15	16	0.771
PAP pressure mmHg	10.6 ± 2	10.6 ± 2.1	0.928

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Table 3. Adverse effects of PAP observed in adherent and nonedherent cases.

	Adherent cases	**Non-adherent cases**	**p value**
	(n = 160)	**(n = 88)**	
Difficulty falling asleep %	18.1	38.1	**0.001**
Sleep disturbances %	26.9	50.6	**<0.001**
Chest discomfort %	10.6	22.6	**0.012**
Machine noise %	31.9	41	0.159
Air leakages %	36.3	45.8	0.149
Skin abrasions and ulcerations %	19.4	20.2	0.872
Dry mouth or nose %	56.3	64.3	0.225
Tooth or jaw pain %	5.6	9.6	0.245
Rhinitis symptoms %	5.6	12	0.077
Morning headache %	17.5	26.2	0.110

Figure 1- The flow diagram

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