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Evaluation of the Daytime Sleepiness in Professional Male Drivers with Obstructive Sleep Apnea: A Clinical Study

Obstrüktif Uyku Apnesi Olan Profesyonel Erkek Sürücülerde Gündüz Uykululuğunun Değerlendirilmesi: Klinik Çalışma

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ABSTRACT Objective: The current study aimed to evaluate the excessive daytime sleepiness (EDS) in professional male drivers with obstructive sleep apnea (OSA) to increase the diagnostic utility of the sleep questionnaires. **Material and Methods:** Fifty-five professional male drivers completed the Epworth Sleepiness Scale (ESS) questionnaire and the Karolinska Sleepiness Scale (KSS) before and after a 50-minute simulator driving task. A hospital polysomnography was conducted to identify patients with OSA. The cutoff 11 on the ESS was used to categorized patients with EDS. The tertial groups were created to examine how the sleepiness levels change across the different ESS scores. **Results:** The median KSS scores increased significantly from 3 points (1-6) to 4 points (1-9) after the driving task. No group differences were found on the delta KSS scores between the patients with vs without EDS. Notwithstanding, there were significant differences between the tertial groups based on the ESS scores [0-4 (non-sleepy), 5-9 (feeling of sleepy), and 10-16 (risk of dozing-off)] (p=0.04). The amount of change in sleepiness level among the first group was significantly lower than the second and the third tertial groups (p=0.02, p=0.004, respectively). In a multivariate regression analysis, the change in sleepiness on the KSS was associated with ESS [standard β=0.39 0.95% confidence interval (0.05-0.23), p=0.004]. The ROC curve analysis indicated that the ESS scores with a cut-off 5.5 had a sensitivity of 77% and a specificity of 66% to predict an increased sleepiness level. **Conclusion:** Drivers with OSA experienced the feeling of sleepiness should be considered as having EDS in the clinical management of OSA.

Keywords: Obstructive sleep apnea; sleepiness; driving

ÖZET Amaç: Mevcut çalışma, uyku anketlerinin tanısal faydasını artırmak için obstrüktif uyku apneli (OUA) profesyonel erkek sürücülerde gündüz aşırı uykululuk (GAU) hâlini değerlendirmeyi amaçladı. **Gereç ve Yöntemler:** Elli beş profesyonel erkek sürücü, Epworth Uykululuk Ölçeği (EUÖ) anketinin yanı sıra Karolinska Uykululuk Ölçeği'ni (KUÖ) 50 dk'lık simülatör sürüş görevi öncesinde ve sonrasında tamamladı. OUA'lı hastaları belirlemek için polisomnografi testi yapıldı. EUÖ'deki eşik puan 11, GAU'lu hastaları tanımlamak için kullanıldı. Farklı EUÖ puanlarının uykululuk durumuna etkisini araştırmak için 3 grup oluşturuldu. **Bulgular:** Medyan KUÖ puanı, sürüş sonrasında 3 puandan (1-6) 4 puana (1-9) önemli ölçüde arttı. KUÖ fark puanları, GAU'sı olan ve olmayan hasta gruplarında farklılık göstermedi. Öte yandan, EUÖ dikkate alarak oluşturduğumuz 3 grup arasında belirgin fark saptandı [0-4 (uykusuz), 5-9 (uykulu hissetme) ve 10-16 (uyuklama riski)] (p=0,004). Birinci gruptaki uykululuk düzeyindeki değişim miktarı, ikinci ve üçüncü gruplara göre anlamlı derecede düşüktü (p=0,02, p=0,004). Regresyon analizi, KUÖ fark puanları ile EUÖ puanları arasında bir ilişki olduğunu doğruladı [standart β=0,39, %95 güven aralığı (0,05-0,23), p=0,004]. ROC eğrisi, uykululuk hâlinin artması durumunu tahmin etmede 5,5 kesme noktasının %77 duyarlılık ve %66 özgüllük değeri ile öngördü. **Sonuç:** Uykululuk hissi yaşayan OUA'lı sürücüler, GAU hâli varmış gibi klinik olarak değerlendirilmelidir.

Anahtar Kelimeler: Obstrüktif uyku apnesi; uykululuk; sürüş

Excessive daytime sleepiness (EDS) is one of the most prominent symptoms in obstructive sleep apnea (OSA), and it is considered as a consequence of sleep fragmentation and associated with loss of alertness.[1] The estimated risk of motor vehicle accidents (MVA) due to the EDS is around 20% and the risk has been enhanced with a two-to seven-fold among the OSA patients with sleepy phenotype.[2] Therefore, the evaluation of EDS and its assessment seems to be crucial in the patients with OSA regarding the high risk of MVAs.

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The key challenge to examine the EDS is a lack of consensus on the definition of daytime sleepiness. Previous studies have been attempted to clarify the concept of sleepiness defining different types.[3] The EDS in OSA is considered as a pathological symptom, compromising two subtypes including habitual and occasional sleepiness.[4] The habitual sleepiness can be defined as more global levels of sleepiness as a trait-like aspect, representing a stable condition. However, the occasional sleepiness is an acute level of sleepiness as a state-like aspect, resulting from the specific environmental factors such as jetlag, medication, driving etc.[3] The interaction between those two concepts has not been studied in OSA population previously.

The aim of the present study is to examine the daytime sleepiness in professional male drivers with OSA in order to improve diagnostic utility of self-evaluation of sleepiness by rating scales.

MATERIAL AND METHODS

PARTICIPANTS

The present study compromised 55 professional male drivers with OSA who were recruited from a sleep clinic in İstanbul, 2020. All participants were invited to voluntarily participant in the current study. A written informed consent has been obtained prior to the study start. The inclusion criteria were defined as having apnea hypopnea index (AHI) above 5 events/night, holding a driving license more than 3 years, have been driving vehicle at least 5 days a week, not having acute illness. Koç University Committee on Human Research approved the study protocol (date: 19 June 2020, no: 2020. 292.IRB2.083). The ethical principles of the Declaration of Helsinki have been considered in the present study.

DATA COLLECTION AND DEFINITION

Demographic characteristics of the study population as well we comorbidities were documented. Obesity was defined as body mass index (BMI) ≥30 kg/m^2. The questionnaires used in routine sleep clinics and the Epworth Sleepiness Scale (ESS) have been applied to each participant during the clinical examination. A full-night hospital polysomnography (PSG) (NOX-A1system: Nox Medical Inc., Reykjavik, Iceland) was conducted including electroencephalography, electrooculogram, leg and chin electromyograms, thoraco-abdominal movements, body position, heart rate and oxyhemoglobin saturation. Based on the AASM 2012 criteria, an obstructive apnea is defined as a at least 90% reduction in airflow for at least 10 seconds in the presence of inspiratory efforts of the upper airway.[5] OSA was defined based on the AHI>5 events/h of the total sleep time.[5]

A fifty-minute simulator driving task was scheduled for each participant between 8:00 and 10:00 in the morning of the PSG testing. The task includes driving performance on the highway, with a low traffic density level aiming to induce drowsiness and to make the driving activity to be sensitive to sleepiness (Figure 1). Each participant was asked to fill out the KSS both before and after the driving task.

ESS

The ESS is a self-reported questionnaire including items asking the likelihood of dozing off or falling asleep in 8 different social circumstances e.g., reading, watching television, riding in a car on a Likert scale of 0-3 total score 0-24.[6] The time frame over which the ratings are made is typically 4 weeks. The

FIGURE 1: Driving simulator task.

ESS score of 11 or more is considered as a clinically significant EDS, and getting higher scores indicate more severe sleepiness.[6] In the present study, the propensity of dozing off was measured as the global sleepiness level using the ESS.

KAROLINSKA SLEEPINESS SCALE

The Karolinska Sleepiness Scale (KSS) is a self-rated questionnaire assessing the subjective level of sleepiness with a 9-point Likert-type scale ranging from 1 to 9; (1) Extremely alert, (2) Very alert, (3) Alert, (4) Rather alert, (5) Neither alert nor sleepy, (6) Some sign of sleepiness, (7) Sleepy, but no difficulty remaining awake, (8) Sleepy, but some effort to keep awake and (9) Extremely sleepy, great effort to keep alert, fighting sleep.[7] Each participant filled out the KSS before and after the fifty-minute driving test. The scale was used to assess the occasional sleepiness in the current study.

STATISTICAL ANALYSIS

Descriptive statistics were summarized as a median with 25th and 75th percentile for the continuous variables, and as a count with percentage for the categorical variables. Normality assumption was tested using Shapiro-Wilk Test. The delta KSS scores were calculated as subtracting the KSS scores at baseline from the KSS scores after the fifty-minute simulator driving. The Mann-Whitney U Test was to analyses the differences between two independent samples. The Kruskal-Wallis Test was used for the multiple groups' comparisons. The Bonferroni correction was applied for the post-hoc analysis in case of a significant test result. Within-group comparisons were carried out with the Wilcoxon Nonparametric Test. The Correlation Coefficients between the ESS and the KSS scores were assessed using Spearman rho. The diagnostic parameters of the ESS were calculated against the change in the KSS scores (increase *vs* no-increase). The receiver-operating characteristic (ROC) curve analysis was conducted to measure the association between the KSS results (increase *vs* no-increase). The accepted significance level for all tests was 0.05 and statistical analyses were performed using IBM SPSS 28.0 for Windows SPSS Inc., Chicago, Illinois, USA.

RESULTS

Baseline demographic and clinical characteristics of the study population have been presented in Table 1. A total of 55 professional male drivers with a mean age of 47.3 (7.4) years has been included to the current study. The mean BMI was 31.6 kg/m^2 (4.1) and a median AHI was 24.4 events/h (14.4-44.5) in the whole study population. Majority of the participants were obese and married.

Out of 55 patients, 36 (65.4%) participants indicated their state as alert or very alert while only 10 (18.2%) patients reported some signs of sleepiness and 2 (3.6%) patients rated themselves as very sleepy on the KSS after a fifty-minutes driving task. Regarding the ESS, majority of the study population reported that the likelihood of falling sleep is high when they are watching TV (56.4%), sitting, and reading (36.4%), and lying down to the rest in the afternoon (36.4%). Interestingly, only 2 (3.7%) patients out of 55, reported a high likelihood of falling sleep in a situation of in a car while stopped for a few minutes in the traffic.

Figure 2 presents that the median KSS score after a fifty-minute driving task was significantly increased from 3 points (1-6) to 4 points (1-9) in the whole cohort. The ESS scores were significantly correlated with the delta scores on the KSS (Figure 3). The delta KSS scores were similar between drivers with EDS *vs* without EDS (*p*=0.10, not shown).

TABLE 1: Baseline characteristics of the study groups.

Study population (n=55)			
Age, yrs.	46.8 (6.7)	Dyspnea, n (%)	15 (27.8)
BMI, kg/m^2	31.4 (3.9)	Hypertension, n (%)	11 (20.8)
AHI events/hour	23.5 (13.7-43.7)	Angina pectoris, n (%)	5 (9.3)
ESS	6 (3-10)	Asthma, n (%)	3 (5.7)
EDS, n (%)	13 (23.6)	AMI, n (%)	3 (5.6)
Marital status, n (%)	49 (90.7)	PCI/CABG	2 (2.8)
Obesity, n (%)	29 (59.2)	Cardiac disease, n (%)	4 (7.4)
Smoking status, n (%)	8 (14.3)	Arrhythmia, n (%)	5 (9.3)
Alcohol use, n (%)	7 (13.0)	Hyperlipidemia, n (%)	7 (13.0)
Allergy, n (%)	6 (11.3)	Diabetes mellitus, n (%)	5 (9.3)

BMI: Body mass index; AHI: Apnea hypopnea index; ESS: Epworth Sleepiness Scale; EDS: Excessive daytime sleepiness; AMI: Acute myocardial infraction; PCI: Persecutive coronary intervention; CABG: Coronary artery bypass graphing.

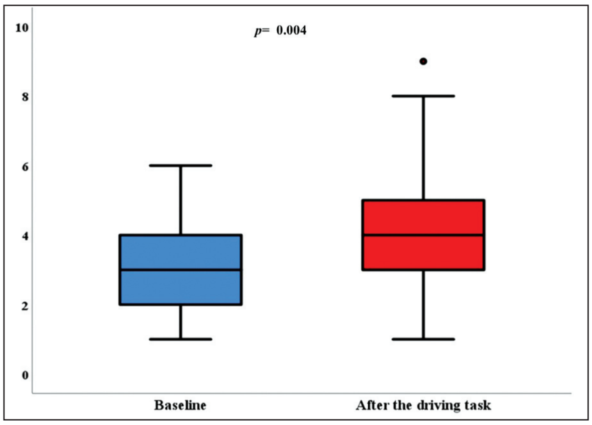

FIGURE 2: Distributions of the total Karolinska Sleepiness Scale scores measured before and after the fifty-minute driving task in the entire study cohort.

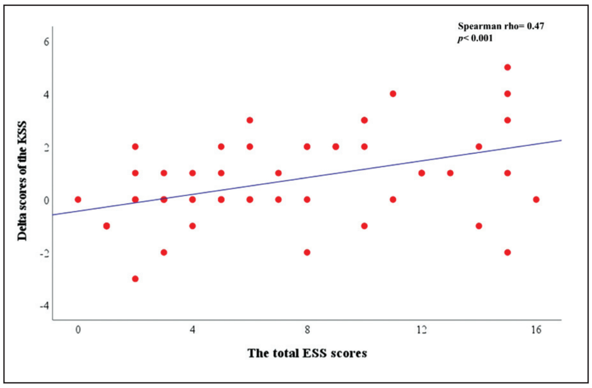

FIGURE 3: Correlation coefficients between the ESS scores and the KSS scores after driving, the delta scores on the KSS.
ESS: Epworth Sleepiness Scale; KSS: Karolinska Sleepiness Scale.

As illustrated in Figure 4, we stratified OSA patients by the tertials (ESS groups with different phenotypes) based on the total ESS scores. The lowest tertial includes drivers with the scores from 0 to 4 points classified as "no sleepiness". The middle tertial group compromises drivers with the scores between 5 and 9 points called as "feeling of sleepiness". The drivers with a score of 10 points and above were included in the last tertial group identified as "risk of dozing off". Baseline demographic and clinical characteristics of the study groups were similar (not shown). Multiple groups comparisons showed that the tertial groups were significantly different regarding the delta scores (p=0.04). Using Bonferroni correction, the post-hoc groups comparisons showed that the delta the KSS scores in the lowest tertial was significantly lower than the middle and the highest tertial groups (p=0.02, p=0.004, respectively).

Linear Regression analysis conducted to examine the association between the delta KSS and the ESS scores in the whole cohort. As reported in Table 2, there is a positive significant association between two test scores after adjusting for the variables age, BMI,

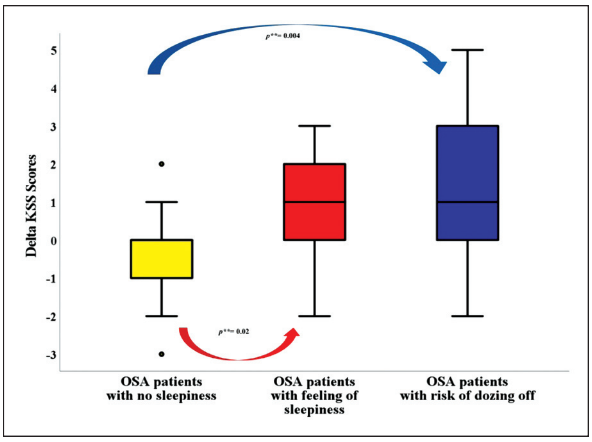

FIGURE 4: Comparison of the amount of change in the KSS scores across the OSA groups with different ESS scores. p** values for the post-doc groups comparisons using Bonferroni corrections.
OSA: Obstructive sleep apnea; ESS: Epworth Sleepiness Scale; KSS: Karolinska Sleepiness Scale.

TABLE 2: Multiple linear regression analysis of the association between the ESS scores and the amount of change in the KSS scores after the fifty-minute driving on the simulator.

	Standardized	95% confidence interval for beta		
	Coefficients beta	Lower bound	Upper bound	p value
Age	-0.04	-0.07	0.05	0.776
BMI	0.21	-0.03	0.18	0.134
AHI	-0.16	-0.03	0.01	0.231
KSS at baseline	-0.27	-0.67	-0.01	0.047
ESS	0.39	0.05	0.23	0.004

ESS: Epworth Sleepiness Scale; KSS: Karolinska Sleepiness Scale; BMI: Body mass index; AHI: Apnea hypopnea index.

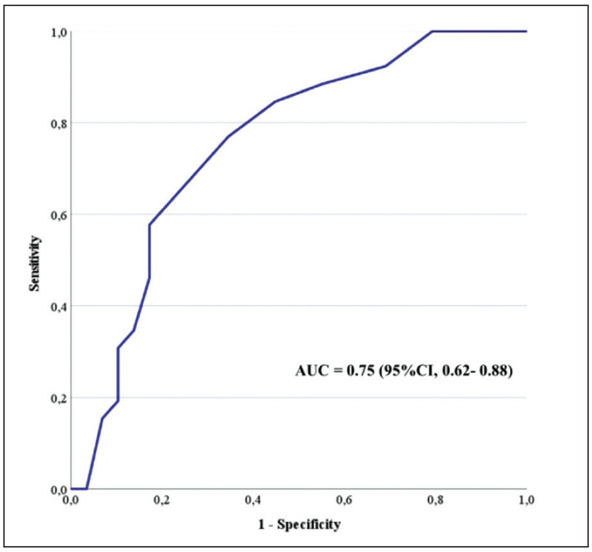

FIGURE 5: Receiver-operating characteristic curve of the association between the Karolinska Sleepiness Scale (with and without sleepiness) and the total Epworth Sleepiness Scale scores.

AHI and the KSS scores at baseline. This result indicates that the participants with increasing ESS scores reported more sleepiness after the fifty-minute driving task on the simulator. Therefore, we run the ROC curve analysis to predict a cut-off score on the KSS which indicates the risk of change in sleepiness due to the driving (Figure 5). The result showed that the ESS scores with a cut-off 5.5 points has a sensitivity of 77% and a specificity of 66% to predict an increase sleepiness level (Figure 5). The area under the curve was 0.75 (95% CI, 0.62-0.88, p=0.001).

DISCUSSION

In the present study, not only OSA patients with the risk off dozing off but also the ones with the feeling of sleepiness reported an increase in their sleepiness levels after a fifty-minute driving activity. This result emphasizes that OSA patients with a milder degree of ESS scores should also be considered as having EDS in the clinical management of OSA. This is especially important to reduce the risk of MVAs.

The current study is the first to evaluate the diagnostic utility of the KSS to predict the change in sleepiness levels during a driving task, and thereby, an important tool to measure fitness to drive in adults with OSA who are at high risk for MVAs. The findings, suggesting an ESS cut-off 5.5 for predicting an increase in the sleepiness level, are quite novel and have important implications for clinical management of the OSA patients as well as for the traffic safety.

In the whole cohort, the sleepiness levels were increased as a result of fifty-minute driving activity on the simulator. The amount of change in sleepiness due to the driving were similar between the drivers with EDS and without EDS. This negative result might be due to the drivers, who reported increased sleepiness after the driving, have been categorized as a subject without EDS based on the ESS cutoff score.

Comparing the OSA patients with different ESS scores, the reported sleepiness levels were not different at baseline. Interestingly, the amount of change in the KSS scores was high among the drivers with feeling of sleep as well as those with risk of dozing off. ROC Curve analysis provided a score of 5.5 on the ESS as a threshold to classify the individual who are likely to have an increased sleepiness after the driving at least fifty minutes. Our results provided evidence supporting previous finding which is OSA patients without EDS have the feeling of sleepiness even though no increase in their ESS scores.[8,9] Therefore, identification of those OSA patients only feel as sleepy seems to be crucial regarding to improved clinical management of those patients and to reduce the risk of MVAs due to sleepiness.

In the context of the daytime sleepiness assessment, the major challenge is the lack of conceptual definition. Despite the large number of studies focused on the sleepiness as a hypothetical construct, there is still no consensus on the definition of sleepiness.[3] In the present study, the ESS was used to assess the global level of sleepiness based on the estimated sleep propensity; while the occasional sleepiness was measured as perception of the need for sleep or the feeling associated with drowsiness using the KSS. Our results demonstrated that not only having risk of dozing off but also having feeling of sleepiness has been associated with increased sleepiness levels after a fifty-minute driving on the simulator. This relationship has not been observed in the OSA patients with EDS. The results indicate that the OSA patients who are having feeling of sleepiness should also be evaluated as having EDS regardless of their scores on the ESS.

To the best of our knowledge, this is the first study examining change in the sleepiness after driving, combining two distinct definitions of sleepiness. Given that EDS is a risk factor for the MVAs, and it is significantly prevalent among the OSA patients, the legislations of driving license have been updated by the international and national committees.[10] The directive from the European Union have been revised regarding the driving licenses of the drivers with moderate to severe OSA may be issued when they show an improvement of daytime sleepiness.[11] The revision of the Turkish legislation has stated that the OSA patients with documented daytime sleepiness should not get the driving license until receiving appropriate treatment.[10] In line with those revisions, a recent report from the American Thoracic Society recommended that the individuals with moderate to severe daytime sleepiness can be classified as a driver with high-risk of MVAs.[12] Regarding the recent updates of the driving license regulations, the evaluation of daytime sleepiness seems to be necessary to reduce the risk of MVAs. We believe that our results contribute new insight indicating that the sleepiness in OSA should be evaluated from different dimensions.

Previous studies have argued that the ESS might not be an adequate on its own for several reasons with the purpose of assessing EDS in clinical practice.[13-16] First, the ESS includes soporific circumstances that do not necessarily enhance the risk of any adverse effect of sleepiness and might not be problematic, such as "lying down to rest in the afternoon" when circumstances permit. Sleeping in such a situation sleep might not indicate any pathological sleepiness overall. This may lead to over diagnosing of subjects who do not have EDS.[3] Second, the patients with insomnia, who has difficulty falling asleep, would likely to have low scores on the ESS due to their low sleep propensity, which may lead to underdiagnosing of subjects with insomnia despite the feeling of sleepiness they experienced.[17] Moreover, a recent study showed subjects with EDS were underdiagnosed since the ESS only measures sleep propensity.[8,9] Lastly, the eight situations assessed by the ESS might show some variations depending on the age, gender, nationality etc.[14,18] The subjects' answers might be affected regardless of their sleepiness. Using different measurements helps to capture different aspect of sleepiness, which provide better diagnostic insight for the pathological sleepiness. In the current study, the KSS was used as an additional assessment tool and evaluated in a combination with the ESS, aiming to improve utility of the sleep questionnaires in the clinical practice to identify OSA patients with the high-risk of MVAs.

The present research has several limitations. The study sample includes only professional male drivers with OSA which limits generalizability of the current findings to the general populations. Furthermore, the drivers included to the current sample might likely to underestimate the sleepiness levels by purpose, regarding the legal issue of driving license. Indeed, a decreased neurocognitive functioning in OSA population might lead to lack of awareness in perception of signal for sleep need.[19] It has also been arguable whether an individual with OSA is truly dissociate the feeling of sleepiness from the risk off dozing off regarding the terminology. Moreover, the symptoms like "tiredness or "fatigue" might be interpreted as sleepiness due to semantic confusion.[20] Another possible limitation could be that the assessment of sleepiness was based on the self-rating questionnaire which includes drawbacks such as unintended bias or falsification. No objective sleep assessment using the multiple sleep latency test has been carried out in the present study due to high cost. Also, no behavioral measures such as Psychomotor Vigilance Test was conducted to measure difference in sleepiness after the driving task.

It is important to acknowledge that the tool used to measure sleepiness should be selected in accordance with a purpose of assessment. Each questionnaire used in the current study has own weaknesses and specific sensitivities, which make them more or less suitable for a specific assessment such as identifying OSA patients with high risk of MVAs due to EDS. Future studies should be focusing on developing an assessment tool capturing multidimensional components of sleepiness including reduced life quality in OSA patients.[21] Such an effort should also include a combination of objective and subjective measurements to evaluate the EDS.

CONCLUSION

The present study indicated the sleepiness in OSA patients should be evaluated in a way that reflects essentially multiple concepts of sleepiness rather than a unitary concept. Increased risk of MVAs in OSA population due to the daytime sleepiness might be associated with an altered night sleep resulted from hypoxia, a specific provoking factor such as the driving which is sensitive to sleepiness and induce drowsiness; or a combination of both. Making distinction between multiple concepts of sleepiness is important not only to reduce the high risk of MVAs but also to improve in diagnostic techniques providing more accurate picture of OSA patients in need of personalized treatment which may increase their life quality.

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Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

This study is entirely author's own work and no other author contribution.

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