Original Article / Çalışma - Araştırma

The reliability of SleepStrip™ as a screening test in obstructive sleep apnea syndrome

Tıkayıcı uyku apnesi sendromunda tarama testi olarak SleepStrip™'in güvenilirliği

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Objectives: This study aims to assess the reliability of SleepStrip™ as a screening test in obstructive sleep apnea syndrome (OSAS).

Patients and Methods: Seventy-two patients (50 males, 22 females; mean age 51.4±11.1 years; range 20 to 74 years) with OSAS were included in this prospective, non-randomized double-blinded single cohort study between May 2008 and February 2009. Patients who underwent an attended overnight polysomnography (PSG) and consented to participate in the study were asked to use SleepStrip™ device within the week following PSG recording. The apnea-hypopnea index (AHI) was compared with the SleepStrip™ score (Sscore).

Results: The mean body mass index of patients was 31.1±4.3. Both AHI and Sscore were obtained in 64 patients. There was a strong correlation between Sscore and AHI (r=0.76, p<0.001). The sensitivity and specificity of the SleepStrip™ were 94.4% and 93.5% when used to diagnose cases with AHI ≥40. The sensitivity and specificity of the SleepStrip™ was reduced to 80% and 87.2% when AHI threshold was chosen as ≥25 and 83.3% and 76.5% for AHI ≥15 respectively.

Conclusion: There is a strong correlation between SleepStrip™ and AHI. SleepStrip™ was found to be effective in diagnosing severe OSAS with AHI ≥40, however, its diagnostic capability was reduced in patients with lower AHI's who constitute the main target of screening.

Key Words: Diagnosis; screening; sleep apnea; snoring; polysomnography.

Amaç: Bu çalışmada SleepStrip™'in tıkayıcı uyku apnesi sendromu (TUAS)'nda tarama testi olarak güvenilirliği araştırıldı.

Hastalar ve Yöntemler: Mayıs 2008 - Şubat 2009 tarihleri arasında ileriye yönelik, randomize olmayan, çift kör ve tek kohort çalışması olarak planan bu çalışmaya TUAS olan 72 hasta (50 erkek, 22 kadın; ort. yaş 51.4±11.1 yıl; dağılım 20-74 yıl) alındı. Tüm gece gözetimli polisomnografi (PSG) çalışması yapılan ve çalışmaya katılmayı kabul eden hastalardan, PSG kaydından sonraki bir hafta içinde SleepStrip™ cihazını kullanmaları istendi. Apne hipopne indeksi (AHİ) ile SleepStrip™ skoru (Sskor) karşılaştırıldı.

Bulgular: Hastaların vücut kütle indeksi ortalaması 31.1±4.3 idi. Hem AHİ, hem de Sskor 64 hastada elde edildi. Sskor ve AHİ arasında kuvvetli ilişki vardı (r=0.76, p<0.001). Apne hipopne indeksinin ≥40 olduğu hastaların teşhis edilmesi istendiğinde SleepStrip™'in duyarlılığı %94.4, özgüllüğü ise %93.5 olarak bulundu. Duyarlılık ve özgüllük AHİ eşiği ≥25 olarak alındığında sırasıyla %80 ve %87.2 ye geriledi; AHİ ≥15 olarak alındığında ise sırasıyla %83.3 ve %76.5 olarak bulundu.

Sonuç: SleepStrip™ ve AHİ arasında kuvvetli bir ilişki vardı. SleepStrip™ AHİ ≥40 olan ağır TUAS tanısının konulmasında etkili olarak bulunmakla beraber, taramanın asıl hedefi olan, daha düşük AHİ'ye sahip hastalarda tanısal etkinliği azalmış olarak bulundu.

Anahtar Sözcükler: Tanı; tarama; uyku apnesi; horlama; polisomnografi.

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Obstructive sleep apnea syndrome (OSAS) is the complex of complete cessation or reduction of airflow during sleep due to repetitive complete or partial collapse of the upper airway leading to asphyxia and arousal and resultant night and day symptoms, hemodynamic changes and complications. Obstructive sleep apnea syndrome is diagnosed when the apnea hypopnea index (AHI) which is measured in polysomnography (PSG) is found to be greater than five. When considered according to this definition, OSAS is a highly prevalent disease that affects the general population. The apnea hypopnea index is greater than five in 24% of the male population and 9% of the female population between the ages of 30 to 60 whereas only 4% of the male population and 2% of the female population are symptomatic.[1] The gold standard for diagnosis of OSAS is PSG, but the availability of PSG is limited and approximately 90% of patients with moderate to severe OSAS at high risk for complications remain undiagnosed.[2] Thus diagnostic screening tests which are suitable for large-scale use are needed. SleepStrip™, developed in 2002 by Shochat et al.[3] is a candidate for such a task.

The aim of the present study was to assess the reliability of SleepStrip™ as a screening test for OSAS.

PATIENTS AND METHODS

Seventy-two patients (50 males, 22 females; mean age 51.4±11.1 years; range 20 to 74 years) who underwent PSG study in the Sleep Laboratory of the Uludağ University School of Medicine, Department of Pulmonary Medicine between May 2008 and February 2009 were asked to participate in the study. Patients who were previously treated for OSAS by means of surgery or positive airway pressure treatments were excluded from the study. Patients were asked to wear a SleepStrip™ device within a week after PSG. Both patient and physician were blinded to the PSG result. Age, sex, body mass index (BMI) and Epworth sleepiness scale (EPSS) were recorded in addition to PSG results and SleepStrip™ score (Sscore) to present patient characteristics.

SleepStrip™ protocol

A SleepStrip™ device was provided to all patients to be used on their own at home. The procedure for use was explained individually to all patients in addition to the guideline provided with the device. Patients were admonished to use the device for at least five hours and sufficient use was confirmed upon return of the device by patients after use. Any discomfort related to the device was also noted. A physician read the Sscore. Sscore recorded as "0", "1", "2" or "3" were considered valid results, any mark apart from these and "E" was considered as an error. Sscores represent the severity of the disease: 0 corresponds to AHI <15, 1 corresponds to AHI 15 to 24.99, 2 corresponds to AHI 25 to 39.99 and 3 corresponds to AHI ≥40

Polysomnography protocol

Full PSG monitoring was performed on all participants using the Compumedics P-series Sleep System (Compumedics Sleep: Melbourne, Australia). Polysomnographic recordings included two electroencephalography channels (C3/A2 and O2/A1), two electrooculogram channels, one submental electromyogram (EMG) channel, and one electrocardiography (ECG) channel. Ventilatory monitoring included recording of oronasal airflow (with an oronasal thermistor), hemoglobin oxygen saturation by pulse oximetry (SaO_2 was measured via a finger oximeter), respiratory movement (with an inductive plethysmograph) including chest, abdomen and body position.

Sleep staging was performed according to the standard criteria of Rechtschaffen and Kales.[4] To assess ventilation during sleep nasal airflow was analyzed carefully. Apnea was defined as an episode of airflow cessation lasting ≥10 seconds. Hypopnea was defined as an episode lasting ≥10 seconds with reductions of thermistor signal amplitude ≥50% and an associated fall of ≥3% in oxygen saturation, or an arousal that lasted ≥10 seconds. Arousals were defined in accordance with the definition of standard criteria.[5] The total number of apneas and hypopneas was divided by the total sleep time to determine the AHI. Apnea hypopnea indices obtained from the patients were graded as 0 (AHI <15), 1 (15 ≤AHI <25), 2 (25 ≤AHI <40) 3 (40 ≤AHI) in order to compare with Sscores.

Statistical analysis

Statistical analysis of the data was performed using the Statistical Package for Social Sciences (SPSS) version 13.0 (SPSS Inc., Chicago, IL, U.S.A.). The correlation analysis of non-parametric data was performed with Spearman's test. The sensitivity and specificity of the Sscores were tested

Table 1. Relationship between apnea-hypopnea index grade and Sscore

	Apnea-hypopnea index grade				
	0	1	2	3	*Total*
Sscore					
0	26	1	3	1	31
1	6	1	1	0	8
2	2	1	2	0	5
3	0	2	1	17	20
Total	34	5	7	18	64

separately against three corresponding AHI levels (>15, >25, >40). Diagnostic accuracy of SleepStrip™ was analyzed by receiver-operator characteristics (ROC) curves with respect to AHI values (Gold standard) using three levels of severity (>15, >25, >40). A p value <0.05 was considered statistically significant.

The Research Ethics Committee of the Uludağ University Faculty of Medicine approved this study.

RESULTS

The mean BMI was 31.1±4.3 (range 21.1 to 40.8) and mean EPSS was 7.7±5.3 out of a possible 24 (range 0 to 19). Two patients did not return the device and could not be contacted. Another two patients were excluded from the study because AHI could not be calculated due to insufficient sleep time (total sleep time <4 hours). The result was accepted as error in seven patients. Four of these patients agreed to use the device again. A valid Sscore was obtained in three of these patients whereas the result was an error in one patient who refused to use the device a third time. Thus, eight out of 75 test results were found as error (10.7%). Five of these results were displayed as error "E" whereas in three cases the mark on the silver screen was unidentifiable. All patients who returned the device confirmed that they had used the device for at least five hours without any discomfort. Three patients had mustaches which did not affect the use of the device.

Sixty-four patients in whom both AHI and Sscores were available were evaluated. Mean AHI was 25.8±27.9 (range 0 to 91.4). The Sscore was 0 in 31 patients, 1 in eight patients, 2 in five patients and 3 in 20 patients (Table 1). There was a strong correlation between AHI and Sscore (r=0.76, p<0.001). Sensitivity and specificity of the SleepStrip™ for diagnosing more serious than mild OSAS (AHI≥15) were 83.3% and 76.5% respectively. Sensitivity and specificity were 80% and 87.2% for an AHI threshold ≥25 respectively. Sensitivity and specificity for diagnosing severe OSAS (AHI ≥40) were 94.4% and 93.5% respectively.

Receiver-operator characteristics curves at three AHI thresholds were plotted in figure 1. The area under curve (AUC) for AHI >15 were 0.80 (p<0.001, 95% confidence interval (CI) 0.68 to 0.89). Area under curve for AHI >25 and AHI >40 were 0.84 (p<0.001, 95% CI 0.72 to 0.92) and 0.94 (p<0.001, 95% CI 0.85 to 0.98) respectively.

DISCUSSION

The American Sleep Association categorized portable tests for OSAS into four levels.[6] According

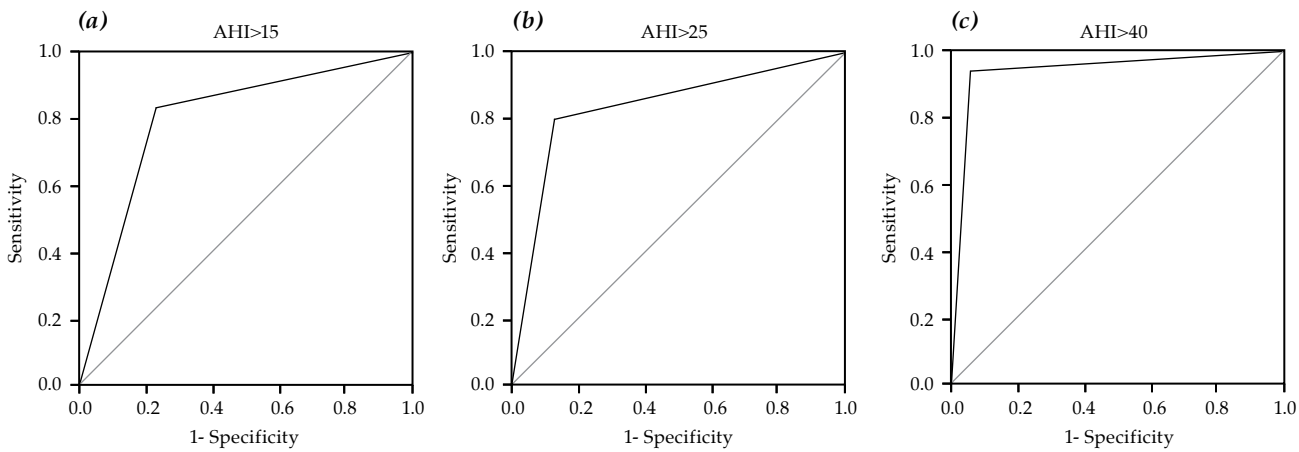

Figure 1. *Receiver operator characteristic curves showing sensitivity and specificity of Sscores at three apnea hypopnea index thresholds of* ***(a)*** *>15,* ***(b)*** *>25 and* ***(c)*** *>40. AHI: Apnea-hypopnea index.*

to this classification; type 1 corresponds to the standard PSG whereas the SleepStrip™ belongs to type 4 that covers devices that monitor single or dual bioparameters. The diagnostic capability of a test generally decreases as the monitored parameters decrease. Therefore the SleepStrip™ does not claim to be an alternative to PSG but a screening device instead. As the SleepStrip™ monitors nasal and oral breathing by the help of three thermistors, it is not able to diagnose arousals, sleep fragmentation, level of hypoxia, type of apnea etc. However, it is able to provide an approximate value of AHI for less effort and cost.

Variable results related to the sensitivity and specificity of SleepStrip™ were reported in the literature. The best results were reported in the pioneer study by Shochat et al,[3] which are concordant with the results of the present study (Table 2). Unlike the present study, Shochat et al.[3] used PSG and SleepStrip™ concomitantly which allowed exact comparison of the two tests. However, the SleepStrip™ was designed as an unattended home study which may reduce its performance. Consequently domiciliary use of the SleepStrip™ should also be tested which was the aim of the present study.

Pang et al.,[7] tested the performance of SleepStrip™ on patients who wore SleepStrip™ at home the night after PSG. Although the study design was almost identical to the present study, Pang et al.[7] found lower sensitivity rates than Shochat's and the present study (Table 2). They discussed the role of night-to-night variability in OSAS and total sleep time as contributors of the discrepancies between studies. The same factors are also valid for the present study.

Hollingworth et al,[8] also tested domiciliary use of the SleepStrip™ device but posted the device to patients. The very low rate of valid results and unfavorable results may have been avoided by personal explanation of the procedure of use to patients. This may also have resulted in a high completion rate as in the present study.

Being a highly prevalent disease that has serious cardiovascular, neurovascular, cognitive complications and increased accident risk, OSAS is an important health problem that merits screening.[9,10]

The SleepStrip™ is easy to use and well tolerated by patients. It is suitable for screening large populations without need of a laborious analysis process. Its cost may be debatable in some countries and its error rate which reached a level of 10% in the present study could aggravate the problem. The SleepStrip™ was found to have high sensitivity and specificity rates especially for AHI values greater than 40. However, the use of SleepStrip™ is not practical in this population as PSG will be necessary in any case. In patients with mild or moderate OSAS in whom screening would be more helpful, the sensitivity and specificity rates decline. Unfortunately few patients had mild or moderate OSAS in the present study, and the results suggest cautious assessment of low Sscores. On the other hand, in order to introduce the value of SleepStrip™ as a screening device, cost-effectivity of the device should be based on larger scale studies.

In conclusion, the SleepStrip™ provided a strong correlation with AHI which was attainable in domiciliary use. However, these results emanated from patients with severe OSAS. On the other hand, the results were vague in patients with lower AHI scores who essentially constitute the main target of screening. Cost-effectivity should also be analysed before qualification as a screening device.

Table 2. Comparison of the results of the SleepStrip™ studies

	Total#	Available#	r	Sens. %	Spec. %	Sens. %	Spec. %	Sens. %	Spec. %
				AHI>10		AHI>20		AHI>40	
Shochat et al.[3]	402	288	0.70-0.86	85-88	52-91	70-85	65-86	75-88	81-94
				AHI≤10		AHI≥20			
Hollingworth et al.[8]	48	17	–	83.3	63.6	14.3	90		
				AHI>15		AHI>25		AHI>40	
Pang et al.[7]	39	32	–	54.6	70	43.8	81.3	33.3	95
				AHI>15		AHI>25		AHI>40	
Present study	74	64	0.76	83.3	76.5	80	87.2	94.4	93.5

#: Number of patients; r: Correlation coefficient; Sens.: Sensitivity; Spec.: Specificity; AHI: Apnea-hypopnea index.

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