Original Article

Diagnostic Accuracy of Home Sleep Apnea Testing (HSAT) in Thai Population

Areerat Ounhasuttiyanon MD[1], Chawanont Pimolsri MD[2], Pakpoom Choeycheep BSc[2], Duangporn Lertsilp MSc[2], Nitipatana Chierakul MD[1]

[1] Department of Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand

[2] Siriraj Sleep Center, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand

Objective: Obstructive sleep apnea (OSA) is a potential serious disorder with a rising prevalence in Thailand. However, underdiagnosis is common as a result of limited diagnostic resources. Home sleep apnea testing (HSAT) has been introduced to replace standard polysomnography (PSG) in certain circumstances. The present study aimed to evaluate the diagnostic accuracy of this uncomplicated ambulatory test.

Materials and Methods: Adult patients without significant cardiopulmonary disease presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA were recruited from the Siriraj Sleep Center in Bangkok. Participants were asked to do a sleep test at home using the HSAT device the day after they had an in-hospital standard PSG.

Results: Eighty-nine participants were recruited between August 2018 and October 2019, but the data were complete in 80 patients. The prevalence of OSA as identified in the PSG was 95%. The diagnostic accuracy of the HSAT was 85%, with an intraclass correlation coefficient of 0.79 (95% CI 0.70 to 0.87) for both tests. For the severity classification, misclassifications that may affect diagnostic phenotyping and therapeutic decision was encountered in 12 patients (15%).

Conclusion: The HSAT had good accuracy for patients with an increased risk of moderate to severe OSA. However, false-negative tests and an underestimation of disease severity should be considered.

Keywords: Home sleep apnea testing (HSAT), Obstructive sleep apnea (OSA), Diagnostic accuracy

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Obstructive sleep apnea (OSA) is a common and potential serious disorder, characterized by repetitive episodes of breathing cessation during sleep. Consequent intermittent hypoxemia and hypercapnia result in fragmented sleep, increased sympathetic nervous activity, and inflammatory cascades. Affected persons may suffer from excessive daytime sleepiness (EDS), cognitive impairment, poor concentration, and emotional lability, which result in declines in one's work capacity and sociability. Furthermore, untreated OSA is associated with increasing cardiovascular risks and metabolic dysregulation, including hypertension, coronary artery disease, heart failure, arrhythmia, stroke, pulmonary hypertension, metabolic syndrome, and diabetes mellitus[1-5]. The prevalence of OSA varies among populations and as a result of the criteria used in diagnosis. The disease's identified prevalence, when using the apnea hypopnea index (AHI) cutoff of five or more events per hour, is estimated to be 24% of men and 9% of women in the United States, compared with 15.4% and 6.3% for men and women in Thailand[6,7].

At present, patients with OSA in Thailand are still underdiagnosed, due to the scarcity of sleep specialists and sleep centers and the significant costs associated with diagnostic tests. For the diagnosis and severity assessment of OSA, the gold standard is polysomnography (PSG), which is not widely available in Thailand. Home sleep apnea testing (HSAT) used out of center and unattended study is an acceptable alternative method[8,9]. The present study aimed to evaluate the diagnostic accuracy of the HSAT, as compared to the PSG. The concordance of disease determination and severity classification between the two tests were also assessed.

Correspondence to:

Chierakul N.

Division of Respiratory Disease and Tuberculosis, Department of Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand.

Phone: +66-2-4197757, **Fax**: +66-2-4197758

Email: nitipatana.chi@mahidol.ac.th

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Materials and Methods

A prospective study involving adult patients with signs and symptoms that indicate an increased risk of moderate to severe OSA was conducted at the Siriraj Sleep Center between August 2018 and October 2019. The patients' clinical characteristics included the presence of EDS and at least two of the following, habitual loud snoring, witnessed apnea, gasping, choking, and diagnosed hypertension[8]. However, those with comorbid conditions that placed the patients at an increased risk of non-obstructive sleep-disordered breathing and other significant non-respiratory sleep disorders such as significant cardiopulmonary disease, neuromuscular conditions, a history of stroke, and central hypersomnolence were excluded. The present study was approved by the Siriraj Institutional Review Board (COA no. Si 345/2018).

After inform consent was completed, participant was asked to do the sleep test at home using the HSAT device (ApneaLink™ Plus, ResMed Corporation, Poway, California, USA) the day after they had the in-hospital standard PSG. The portable monitor, also called respiratory polygraphy, included sensors for airflow, respiratory effort, and pulse oximetry readings. The patients brought the device to their home after being given a detailed explanation and a functional test device by a technician at the hospital. After the device was returned the following day, the raw data files were transmitted to a computer and scored automatically, excluding the artifact periods.

Demographic data including the person's age, gender, body mass index (BMI), co-morbidities, and presenting symptoms were recorded. Polysomnographic parameters were also collected, which identified the sleep time, the AHI from the PSG, the respiratory event index (REI) from the HSAT, the apnea index, and the hypopnea index. The diagnosis of the OSA was verified from a manual scoring of the PSG using the standard procedures of the American Academy of Sleep Medicine (AASM) Task Force[10]. Mild, moderate, and severe OSA are characterized by sleep-related obstructive respiratory events: 5 to less than 15, 15 to less than 30, and 30 or more events per hour, respectively[11].

From the previous studies evaluating the performance of HSAT devices against the PSG, with an accuracy in a high-risk population, those with a prevalence of more than 80%, ranging from 84% to 91%, the sample size should be at least 73 patients. A mean and median were used to describe the data according to the distribution, and agreement between the HSAT and the PSG were assessed using the intraclass correlation coefficient. A p-value of less than 0.05 was considered statistically significant. PASW Statistics for Windows, version 18.0 (SPSS Inc., Chicago, IL, USA) was used for the analyses.

Table 1. Baseline clinical characteristics of 80 patients

Parameter	n (%)
Age (years); mean±SD	46±13
Body mass index (kg/m^2); mean±SD	28.7±3.9
Sex: male	55 (68.8)
Co-morbidities	
Hypertension	38 (47.5)
Diabetes mellitus	10 (12.5)
Dyslipidemia	22 (27.5)
Presenting symptoms	
Habitual loud snoring	80 (100)
Breathe pause or choking	63 (78.8)

SD=standard deviation

Results

The authors recruited 89 participants during the study period. After the portable recording machine was returned, technical adequacy and complete data were established for only 80 patients. Most of them were males with a high BMI, and nearly half of them had hypertension. The demographic data and clinical information are shown in Table 1.

The prevalence of OSA according to the PSG was 95%, and it was 85% from the HSAT. For total respiratory events, either AHI or REI, a lower number was observed in the HSAT at 32 versus 15.3 events per hour, and obviously from the low hypopnea at 19.3 versus 5.9 events per hour rather than the apnea at 6.1 versus 6.5 events per hour. Other polysomnographic data are shown in Table 2. The diagnostic accuracy of the HSAT was 85%, with good reliability and intraclass correlation coefficients [0.79 (95% CI 0.70 to 0.87), p<0.001].

Concordance between any severity of OSA from HSAT and PSG recording is shown in Table 3. The HSAT misclassified no OSA into mild OSA in two patients. This could lead to over-prescribing positive airway pressure (PAP) therapy. Meanwhile, HSAT misclassified mild OSA into no OSA in seven patients, and moderate OSA to no OSA in three patients. This could lead to under-prescribing the PAP therapy. The overall numbers of misclassifications that could lead to a false management plan was 12 out of the 80 patients (15%).

Table 2. Baseline laboratory characteristics of 80 patients

Outcome	PSG; n (%)	HSAT; n (%)
Number of OSA patients	76 (95.0)	68 (85.0)
Mild OSA	14 (17.5)	26 (32.5)
Moderate OSA	20 (25.0)	21 (26.3)
Severe OSA	42 (52.5)	21 (26.3)
AHI or REI (events/hour); median (IQR)	32 (15.4 to 69.9)	15.3 (7.1 to 30.9)
AI (events/hour); median (IQR)	6.1 (1.2 to 25.1)	6.5 (1.9 to 22.8)
HI (events/hour); median (IQR)	19.3 (10.6 to 33.8)	5.9 (2.9 to 10.7)
Total sleep time (hour); mean±SD	4.6±2.2	4.9±2.3

PSG=polysomnography; HSAT=home sleep apnea testing; OSA=obstructive sleep apnea; AHI=apnea-hypopnea index; REI=respiratory event index; AI=apnea index; HI=hypopnea index; IQR=interquartile range; SD=standard deviation

Table 3. Concordance between HSAT and PSG

HSAT	PSG			
	No OSA	Mild	Moderate	Severe
No OSA	2	7*	3*	0
Mild	2*	5	13	6
Moderate	0	2	4	15
Severe	0	0	0	21

HSAT=home sleep apnea testing; PSG=polysomnography; OSA=obstructive sleep apnea

* Misclassified patients with potential false management plan

Discussion

The gold standard for management of patients suspected to have OSA is in-laboratory PSG. However, this modality is expensive, time-consuming, and is under-available in limited-resources settings. A home respiratory polygraphy or HSAT may be a simpler and cheaper alternative to an in-laboratory PSG for the management of patients with a high clinical suspicion of OSA eligible to continuous positive airway pressure (CPAP) treatment if OSA was demonstrated.

In the present study of Thai patients, a high accuracy of the HSAT for the diagnosis of OSA in adult patients with signs and symptoms indicate an increased risk of moderate to severe OSA was achieved, with good reliability, as compared to the gold standard PSG. The accuracy was comparable to other studies in different populations[12-14]. For the severity misclassification in the present study, this may result from a lower detection rate of hypopnea events associated with cortical arousals by HSAT. In term of post-procedural management, access to CPAP therapy was not different for those with OSA with discordant severity, as all of them were symptomatic. Corral et al, have demonstrated that the long-term effectiveness of management strategies relying on the HSAT was not different, in terms of the clinical outcomes, as compared to the PSG-based considerations[12].

Although misdiagnosis of no OSA was observed in 10 of 76 patients (13.1%) of the studied patients, it did not occur in the severe OSA patients. However, it might not be harmful if physicians followed the guidelines recommended by the AASM that if a single HSAT is negative, inconclusive, or technically inadequate, the PSG should be done if a high index of suspicions exist. The application of machine-learning models may improve the predictions regarding which patients are likely to require PSG after an initial non-diagnostic HSAT, irrespective of etiology[15].

The authors intended to use an automatic scoring system to suit the real-world practices of sleep medicine in Thailand, where the number sleep specialists are insufficient. Using standard manual analysis (MA) over automatic analysis (AA) has been propagated, despite the weak evidence for this recommendation[8]. Labarca et al, have shown that the AA underestimated the respiratory events of eight events per hour (95% CI seven to nine events per hour, $p<0.001$), and that it delivered a false severity by 47%, especially in patients with mild to moderate disease[16]. Notwithstanding this, with current technological advancements in the apparatus used in the present study, the misdiagnosis and misclassification rates in the present study were only 13.1% and 15%, respectively.

Interestingly, among four patients with a negative PSG in the present study, two of them had a positive HSAT categorized as mild OSA. False negatives in the PSG, as compared to the HSAT, especially among the elderly, has been raised as a concern by specialists, and has led to the conclusion that this is a downside of the PSG, as compared to the HSAT, for patients who have difficultly falling asleep in different environments[17]. The first-night effects of the in-hospital setting for the standard PSG, along with night-to-night variabilities in the respiratory events, may explain this phenomenon.

In terms of longitudinal care, a follow-up HSAT, rather than a complex PSG for collecting objective data that can help improve or confirm treatment efficacy, should be also considered. However, technical error in HSAT monitoring should be considered, the prevalence was 10.1% (9 of 89 patients) in the present study.

Conclusion

HSAT is feasible and reliable for the adult Thai population, with a high pretest probability of OSA. However, negative results must be handled with care.

What is already known on this topic?

HSAT has been wildly used in Western countries to detect OSA in high-risk patients.

What this study adds?

The application of the HSAT in the management plan of adult Thai patients with a high index of suspicions for OSA is feasible and has high diagnostic accuracy. Negative or inadequate studies should be considered when performing subsequent standard PSG to verify the existence of this potentially harmful disease.

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Conflicts of interest

The authors declare no conflict of interest.

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