

Home-based diagnosis of obstructive sleep apnea by polysomnography type 2: accuracy, reliability, and feasibility

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Abstract

Purpose Despite being used in large cohort studies, role of polysomnography (PSG) type 2 is still controversy. This study was aimed to determine its accuracy, reliability, and feasibility in diagnosis of obstructive sleep apnea (OSA) compared to gold standard.

Methods Adult patients with stable medical conditions who complained of snoring or excessive sleepiness and lived around Bangkok were recruited from a sleep clinic. All were asked to fill questionnaires and have PSG done in laboratory (in-Lab PSG) and at home (Home PSG) on separate nights within 2–4 weeks interval.

Results Eighty-six patients, 48 males and 38 females, were included. Mean of total sleep time, sleep efficiency, and stage R were significantly greater in Home PSG than in-Lab PSG ($p < 0.05$). Apnea–hypopnea index (AHI) was slightly higher in Home PSG (25.7 versus 23.5, $p = 0.04$), but with excellent reliability, intra-class correlation coefficients of 0.96 (95 % CI; 0.93–0.97), and good agreements ($\kappa = 0.59–0.70$) between both tests. The sensitivity, specificity, and accuracy of Home PSG at cut-off point of $AHI \geq 5$, were 0.97, 0.56, and 0.85, respectively, and at $AHI \geq 15$ were 0.95, 0.76, and 0.85, respectively. Sixty-four patients (74.4 %) preferred home-PSG but four patients (4.7 %) needed repeated tests due to significant data loss.

Conclusions This is the first report in Asia demonstrating that home-based diagnosis of OSA by PSG type 2 was feasible

performing with good reliability, high accuracy, and a low failure rate. However, further studies focusing on its cost-effectiveness are required.

Keywords Home polysomnography · Portable monitoring type 2 · Sleep study · Obstructive sleep apnea · Sleep-disordered breathing · Accuracy · Reliability · Feasibility

Introduction

Obstructive sleep apnea (OSA) is a common disorder in which the upper airway repetitively narrows or collapses during sleep and results in oxygen desaturation or sleep disruption leading to several health consequences such as impaired quality of life [1], hypertension [2], and increased cardiovascular-related mortality [3–5]. Although, several studies had demonstrated a well-known “first night effect” of sleep architecture and “night-to-night variations” in the severity of OSA [6–11], polysomnography (PSG) or a sleep test attended by technical staffs in a laboratory (in-Lab PSG) is still routinely indicated for the diagnosis [12, 13]. However, its high cost, long waiting list, and unfamiliar setting have made this gold standard test inconvenient for several patients. Under these conditions, portable sleep monitoring may be used as an alternative diagnostic method, particularly for patients with a high pretest likelihood of moderate to severe OSA, when it was utilized as a part of comprehensive sleep evaluation [13, 14].

Comprehensive portable PSG, study type 2 (level II) according to the American Sleep Disorder Association (ASDA) standards of practice [15], is another method to measure important sleep and respiratory parameters which are almost similar to the gold standard, except for the absence of trained personnel or sleep technician to ensure continuous recording quality. This type of study is potentially an excellent

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alternative method for OSA diagnosis which can be performed in a home setting (Home PSG). It had been validated and extensively utilized in large multicenter cohort studies such as the Sleep Heart Health Study (SHHS) [16–19], Sleep Action for Health in Diabetes (Sleep AHEAD) [20], and the Tucson Children's Assessment of Sleep Apnea study (TuCASA) [21]. The recent study of Campbell et al. [22] also demonstrated that the home set-up PSG was valid and technically reliable with similar success rate to the SHHS. Its advantages over an in-Lab PSG include the providing of most familiar sleep environment for patients, a cost reduction from the absence of an overnight hospital stay, and more chances for sleep technicians to sleep regularly at nighttime when returning home after work. Nevertheless, its routine clinical use has not been supported by the American Academy of Sleep Medicine (AASM) since there was insufficient clinical data, particularly on its sensitivity and specificity compared to the gold standard [14, 23]. The major limitation of Home PSG is the absence of overnight monitoring by a sleep technician to handle problems or initiate treatment during the test. In addition, some disadvantages such as a transportation problem of sleep technicians and a high failure rate due to significant signal loss have been reported [24, 25]. In order to clarify these controversies, this study was designed to assess the accuracy, reliability, and feasibility of the Home PSG in diagnosis of OSA compared to the gold standard in-Lab PSG. We believed that this study may provide additional perspectives to its role in clinical practice, at least from an Asian country.

Methods

This study was conducted at Siriraj hospital between September 2011 and January 2013 after an approval from Siriraj Institutional Review Board (SIRB). All participants were recruited with consent forms after being explained about the procedures.

Subjects

Eighty-six consecutive patients, 48 males and 38 females, aged ≥ 18 years old who complained of snoring or excessive sleepiness (self-reported) were recruited from Siriraj sleep clinic. Pregnant women or patients who had significant comorbid medical conditions such as congestive heart failure, severe pulmonary disease, and neuromuscular disease were not included in the study which is in accordance with the recommendation of the AASM guideline [14]. Any patients who were regular shift workers, lived outside Bangkok or nearby provinces (< 80 Km by estimation from our hospital), had total sleep time < 2 h, and had no rapid eye movement sleep (stage R) during in-Lab standard PSG were excluded

from the study. All patients were asked to complete questionnaires regarding sleep habits and related symptoms, Epworth Sleepiness Scale (ESS) [26], underlying medical illnesses, and physical examinations as parts of a routine clinical care. Questions (Q) regarding subjective sleep evaluation included: Q1 sleep quality (cannot sleep, restless sleep, normal sleep), Q2 number of awakening after sleep onset (none, once, twice, three times, four times, or more), Q3 difficulty falling asleep (none, mild, moderate, severe), Q4 discomfort or unpleasant feeling (none, mild, moderate, severe), Q5 feeling of hurt or irritation (none, mild, moderate, severe), Q6 feeling of unsafe or insecurity (none, mild, moderate, severe), Q7 more convenience (in-Lab PSG or Home PSG), and Q8 preference after being tested if results from both are equal (in-Lab PSG or Home PSG). All patients were classified by their diseases' severity by apnea-hypopnea index (AHI) into the followings; primary snoring (AHI=0–4.99), mild OSA (AHI=5–14.99), moderate OSA (AHI=15–29.99), and severe OSA (AHI ≥ 30).

Polysomnography type 1 (in-Lab PSG)

All gold standard overnight technician-attended PSG (Compumedics, Somte, Profusion III software, Victoria, Australia) were performed at Siriraj hospital. Their recordings included electroencephalogram (EEG) measured at C4-M1, F4-M1, and O3-M2, bilateral electro-oculogram (EOG), electromyogram (EMG) measured at submental and anterior pretibial area, electrocardiogram (ECG), airflow measured with both nasal pressure transducer and thermistor, respiratory efforts measured from thoracic and abdominal movement (piezoelectric crystal), body-position sensor, and pulse oximetry measured at finger with maximum signal averaging time of ≤ 3 s. Real-time video recordings were performed as routine. Light-off started when patients felt sleepy and ready to go to bed, and the recording ended (light-on) when they woke up. All PSG parameters were scored manually by well-trained sleep technologists and reviewed by international sleep specialists certified by American Board of Sleep Medicine (ABSM).

Polysomnography type 2 (Home PSG)

All unattended Home PSG (Grass Telefactor AURA, Twin software, Rhode Island, USA) were set up at patients' home by a sleep technician within 2–4 weeks after gold standard PSG. The off-line ambulatory recordings consisted of two EEG channels (C3-M2 and O4-M1), two EOG channels, chin EMG, nasal thermistor, thoracic and abdominal respiratory effort bands, body-position sensor, and pulse oximetry with averaging time similar to an in-Lab PSG. Battery power supply and memory storage card of recorded data were set up within an acquisition box attached on patient's chest wall. All patients were advised to sleep in their usual positions and

not to drink alcohol or sleeping pills since they could interfere with the results. Light-off started when patients reported that they stayed in bed and were ready to sleep which could be confirmed by their supine or lateral sleep position in the PSG tracings. Light-on was set at patients' time to wake up depending on their reports. After completion of the recording, the device was removed and picked up by a research coordinator in the following morning. All data were extracted from the memory storage card and sent to another computer for manual scoring by a well-trained sleep technologist and for reviewing by an international sleep specialist certified by ABSM who was blinded to the results of in-Lab PSG during study by concealment of patients' identification.

Definition of sleep-related parameters

For both in-Lab and Home PSG, the sleep parameters and respiratory events were scored according to standard criteria recommended by AASM 2007; first version [27]. AHI was defined as the number of apnea plus hypopnea events per hour of sleep. Apnea was defined as a reduction of airflow amplitude of $\geq 90\%$ for at least 10 s and hypopnea was defined as a reduction of airflow amplitude of $\geq 30\%$ for at least 10 s and oxygen desaturation of at least 4 % from the pre-event baseline. We did not use new definition of hypopnea as recommended in the AASM manual of scoring version 2 since it was not used in previous reports of the SHHS and several studies [1, 2, 4, 16, 17, 19, 20]. Any study that had significant data loss or major artifacts such as unclassified sleep staging or poor airflow signal of more than 80 %, oxygen saturation of 0 %, and total sleep time of less than 120 min was considered as an unreliable or failed PSG.

Statistical methods

Continuous data were presented in mean \pm standard deviations (SD) and categorical data were presented as frequencies and percentages (%). The diagnostic properties of Home PSG in diagnosis of OSA compared to the gold standard in-Lab PSG were described as sensitivity, specificity, positive predictive values (PPV), negative predictive values (NPV), and accuracy at typical AHI cut-off points of 5 and 15. To measure the reliability of AHI between both tests, the intra-class correlation coefficients (ICC) were used. To determine the degree of classification agreement according to the severity of disease between home and in-Lab PSG, the kappa (κ) coefficients was used. A Bland–Altman plot of the difference in AHI relative to mean AHI was used to assess the threshold for differences. To compare sleep parameters and patient's perception or subjective evaluation between in-Lab and Home PSG, paired *t* test or Wilcoxon's signed rank test and Chi's square test were used for continuous and categorical data, respectively. The computer program used for calculation was the Predictive Analytics

Software (PASW) Statistics version 18.0 (New York, USA). Significant level was accepted at $p < 0.05$ in two-tailed tests.

Results

There were 86 patients, 48 males and 38 females, with ages ranging from 18 to 74 years recruited in this study. Mean ESS score and body mass index were 10.5 ± 3.6 and 26.6 ± 4.0 , respectively. Important sleep parameters of both in-Lab and Home PSG of all participants are shown in Table 1. There were four out of 86 patients (4.7 %) who failed the Home PSG and required repeated studies due to significant data loss related to oximetry probe and the EEG signals. However, no failure was found in these second tests. The diagnostic properties of the Home PSG compared to gold standard test in diagnosis of OSA at the typical AHI cut-off points are presented in Table 2. The reliability of AHI scoring between both PSG was excellent as shown by ICC of 0.96 (95 % CI, 0.93–0.97) and the graph of a linear correlation in Fig. 1. The mean AHI bias (mean difference of AHI \pm SD) between in-Lab and Home PSG was 2.2 ± 9.6 . A Bland–Altman plot of the differences of AHI relative to mean AHI of both tests is shown in Fig. 2. The classification of OSA severity in both Home and in-Lab PSG is presented in Table 3 which demonstrates a

Table 1 Important sleep parameters of all patients

	In-lab PSG (N=86)	Home PSG (N=86)	<i>p</i> value
Total sleep time (min)	388.9 \pm 60.1	437.4 \pm 55.7	<0.001 ^b
Sleep latency (min)	7.7 \pm 7.9	2.6 \pm 2.5	<0.001 ^b
REM latency (min)	118.8 \pm 70.0	101.3 \pm 46.3	0.032 ^a
Time in supine (min)	248.1 \pm 127.8	207.7 \pm 131.2	0.002 ^a
Sleep efficiency (%)	83.3 \pm 11.6	87.7 \pm 7.4	0.002 ^a
Stage N1 (%)	22.0 \pm 16.0	15.3 \pm 8.2	<0.001 ^b
Stage N2 (%)	47.8 \pm 12.4	54.9 \pm 8.0	<0.001 ^b
Stage N3 (%)	13.2 \pm 9.9	10.3 \pm 5.7	0.002 ^a
Stage R (%)	16.7 \pm 5.7	19.5 \pm 5.3	<0.001 ^b
AHI (events/h)	23.5 \pm 24.9	25.7 \pm 22.9	0.035 ^a
AHI in supine	29.6 \pm 27.4	32.8 \pm 27.8	0.09
AHI in non-supine	8.9 \pm 15.4	15.4 \pm 21.6	0.001 ^a
AHI in REM	25.9 \pm 23.2	32.8 \pm 25.9	0.001 ^a
AHI in NREM	23.4 \pm 26.3	23.7 \pm 23.6	0.78
Mean O ₂ (%)	93.9 \pm 3.9	93.9 \pm 4.1	0.78
Time O ₂ \geq 90 % (%)	90.4 \pm 18.2	92.6 \pm 13.1	0.07

The data are presented in mean \pm standard deviation

PSG polysomnography, AHI apnea–hypopnea index, REM rapid eye movement, NREM non-rapid eye movement, O₂ oxygen saturation, Time O₂ \geq 90% time spent in oxygen saturation of more than 90 %

^a The mean difference is significant at the level of <0.05 (two-tailed)

^b The mean difference is significant at the level of <0.001 (two-tailed)

Table 2 Properties of home polysomnography compared to gold standard in-lab polysomnography in diagnosis of obstructive sleep apnea

Cut-off points	Sensitivity (95 % CI)	Specificity (95 % CI)	PPV (95 % CI)	NPV (95 % CI)	Accuracy (95 % CI)
AHI ≥ 5	96.7 (87.6–99.4)	56.0 (35.2–75.0)	84.3 (73.2–91.5)	87.5 (60.4–97.8)	84.9 (76.1–88.7)
AHI ≥ 15	95.1 (82.2–99.2)	75.6 (60.1–86.6)	78.0 (63.7–88.0)	94.4 (80.0–99.0)	84.8 (75.3–88.7)

The data are presented in percentages (%)

AHI apnea-hypopnea index, PPV positive predictive value, NPV negative predictive value, CI confidence interval

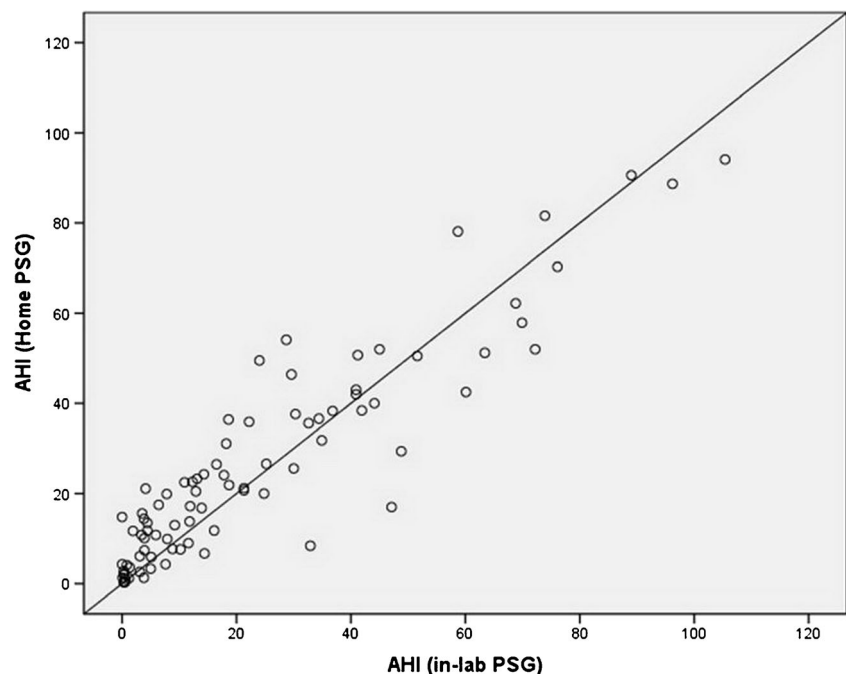
moderate degree of agreement when using cut-off point at AHI ≥ 5 ($\kappa=0.59$) and a good agreement when AHI ≥ 15 ($\kappa=0.7$). Patient's perception or subjective evaluation of both in-Lab and Home PSG is presented in Table 4. A majority of the patients reported their better sleep quality during Home PSG than during in-Lab PSG and 64 patients (74.4 %) would choose the Home PSG if both methods were offered simultaneously. They also informed us that their discomforts during in-Lab PSG were mainly due to extensive sensor wirings and unfamiliar environment, while those of Home PSG were predominantly due to a heavy pressure of an acquisite box attached on their chest walls and a fear of sensor detachment. No serious adverse event was found in this study.

Discussion

Although an in-Lab PSG remains a gold standard diagnostic test for OSA, its high cost, long waiting list, and first night

effect from an unfamiliar setting have made it unsuitable for several patients. In such a case, PSG type 2 which measures similar parameters at patient's home without an attending technician may be an interesting alternative method. However, its role in current clinical practice is still controversial and is not recommended by AASM for routine use due to insufficient data [14, 23]. This study have shown that the reliability of AHI scoring between the Home PSG and in-Lab PSG was excellent with an ICC of 0.96 (95 % CI, 0.93–0.97) which was slightly higher than those of other studies [19, 28, 29]. The sensitivity of Home PSG was more than 95 % with accuracy of 85 % when using AHI cut-off points at 15 for the diagnosis of OSA, which was comparable to the study of Bruyneel et al. [28] and Campbell et al. [22]. The specificity for Home PSG was not as good as sensitivity but it increased when using a higher AHI cut-off point for diagnosis. The mean AHI of the Home PSG was slightly higher than those of in-Lab PSG, especially during REM sleep. There were 11 from 25 patients (44 %) who were initially diagnosed as PS (AHI <5) by the in-Lab PSG but were

Fig. 1 Correlation between apnea–hypopnea index (AHI) of in-lab polysomnography (X-axis) and home polysomnography (Y-axis)



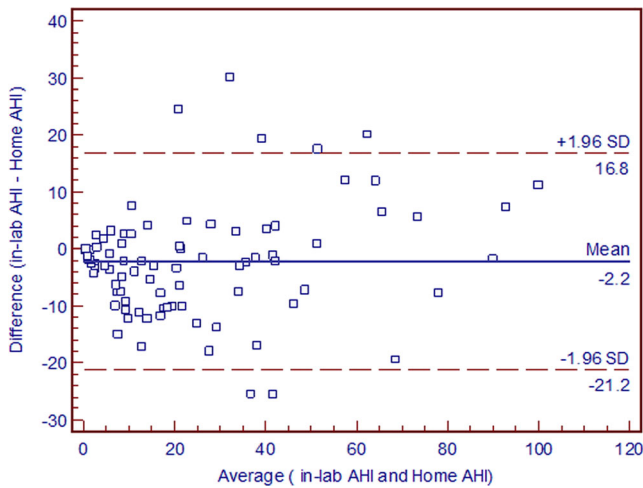


Fig. 2 Bland–Altman plot of the difference of apnea–hypopnea index (AHI) between in-lab and home polysomnography (Y-axis) in relation to the mean AHI of both tests (X-axis): the mean difference (bias) was near zero and the confidence limits were 1.96 standard deviation. There was a trend to be more scatter at AHI of higher than 20

found to be OSA (AHI ≥5) by subsequent Home-PSG as shown in Table 3. These results were in accordance with several reports that a single negative in-Lab PSG may not always exclude the diagnosis of OSA and repeated tests sometimes reveal different information due to night-to-night variability in sleep [6, 8–11]. The discrepancies between both types of PSG in diagnosis of OSA were also possibly related to differences in REM amount, alcohol assumption, medication, and nasal congestion that can vary between hospital and home and from one night to another. Although we could not explain exactly why the AHI were slightly higher at home even considering that the use of the thermistor may underestimate the number of hypopneas as compared with nasal cannula of in-Lab PSG in this study, our hypotheses are that it was due to the greater amounts of time spent in stage R as shown by the significant higher REM AHI at home than those of the in-Lab PSG, and probably the natural course of OSA or night-to-night variability of the disease.

Table 3 Classification of obstructive sleep apnea severities compared between home polysomnography and in-lab polysomnography

		Home PSG				Total
		PS	Mild	Moderate	Severe	
In-lab PSG	PS	14	9	2	0	25
	Mild	2	9	9	0	20
	Moderate	0	1	7	6	14
	Severe	0	1	3	23	27
Total	16	20	21	29	86	

The data are presented in number of cases
PSG polysomnography, PS primary snoring

Table 4 Comparison of patient’s perception or subjective evaluation between home polysomnography and in-lab polysomnography

	In-lab PSG N (%)	Home PSG N (%)	p value
1. Sleep quality			
Cannot sleep	9 (10.5)	2 (2.4)	<0.001 ^b
Restless sleep	44 (51.2)	31 (36)	
Normal sleep	33 (38.3)	53 (61.6)	
2. Number of awakening after sleep onset			
None	1 (1.2)	5 (5.8)	0.001 ^a
Once	19 (22.1)	28 (32.6)	
Twice	27 (31.4)	25 (29.1)	
Three times	23 (26.7)	23 (26.7)	
Four times or more	16 (18.6)	(5.8)	
3. Difficulty falling asleep			
None	24 (27.9)	27 (31.4)	0.005 ^a
Mild	29 (33.7)	40 (46.5)	
Moderate	19 (22.1)	18 (20.9)	
Severe	14 (16.3)	1 (1.2)	
4. Discomfort or unpleasant feeling			
None	15 (17.4)	18 (20.9)	0.14
Mild	38 (44.2)	44 (51.1)	
Moderate	28 (32.6)	20 (23.3)	
Severe	5 (5.8)	4 (4.7)	
5. Feeling of hurt or irritation			
None	50 (58.1)	50 (58.1)	0.69
Mild	28 (32.6)	27 (31.4)	
Moderate	8 (9.3)	8 (9.3)	
Severe	0 (0)	1 (1.2)	
6. Feeling of unsafe or insecurity			
None	47 (54.7)	56 (65.1)	0.12
Mild	31 (36.0)	24 (27.9)	
Moderate	7 (8.1)	4 (4.7)	
Severe	1 (1.2)	2 (2.3)	
7. More convenience			
	22 (25.6)	64 (74.4)	
8. Preference after being tested if results from both are equal			
	22 (25.6)	64 (74.4)	

The data are presented in number (percentages)

^a The mean difference is significant at the level of <0.05 (two-tailed)

^b The mean difference is significant at the level of <0.001 (two-tailed)

With regard to sleep quality, this study demonstrated that the sleep architectures of patients obtained from Home PSG were slightly better than those of in-Lab PSG. During Home PSG, there were significantly more total sleep time, a better sleep efficiency, more stage R, while there were less stage N1 and a reduced REM latency. These findings were in accordance with the previous reports of Bruyneel [28], Kingshott [7], and Iber et al. [19], but different from those of Portier [25], Gagnadoux [30], and Fry et al. [24]. The majority of our patients also reported that they had a better sleep quality with

a smaller number of awakenings after sleep onset during Home PSG and would select the Home PSG as their preferred option since they had more flexibility of schedule and sleep position at their own homes. Therefore, our study supported the common belief that patients would prefer the convenience of having PSG done at home which was similar to the report of Bruyneel [28] and Campbell et al. [22], but contrast to those of Fry [24], Portier [25], and Gagnadoux et al. [30]. The very short sleep latency during both in-lab and home settings in this study was possibly due to the light-off time which started when the patients already stayed in bed and were sleepy enough to sleep shortly. Since there was no technician attended during Home PSG, the light-off time would be based on only the time reported by patients and the position shown in PSG findings which might be different from that of in-Lab PSG.

Although some studies highlighted technical difficulties leading to a failure of Home PSG [25, 30], there were only four out of 86 patients (4.7 %) who required repeated tests due to technical errors such as detachment of sensors or severe artifacts in this study. Our low failure rate was equal to those of Bruyneel et al. [28], but slightly higher than those of Chung et al. [31] who reported a failure rate of 2.3 %, and Fry et al. [24] who reported a technical failure rate of approximately 4 % during Home PSG. Nonetheless, it was substantially lower than those of 23.4 % reported by Gagnadoux et al. [30], and 20 % reported by Portier et al. [25] whose studies were done in French patients who were fitted with monitoring devices in sleep laboratories and returned home to sleep with a risk of electrical lead detachment while traveling. The failure rate of our Home PSG was also slightly less than those of Kapur et al. [18] and Goodwin et al. [21]. We believed that the stability of our Home PSG recordings was possibly related to the service of a well-trained sleep technician who set up the device at patient's home; this was in agreement with previous reports [22, 24, 28, 31].

There were some limitations in this study. Firstly, we recruited only patients with a relative good health status who resided within Bangkok or nearby provinces. Our reasons were that patients with unstable or poor health status were preferentially recorded in the sleep lab where there were sufficient medical personnel and equipment readily prepared for adverse events. However, if patients are in stable medical condition, adverse effects will not be due to the sleep test but to hazard (heart attack, stroke, arrhythmias, etc.) which can occur in both home and hospital settings. In addition, it was inconvenient for our technician to travel beyond those areas because of the traffic problems. Therefore, our results might not be applied to rural area where no certified sleep technician was available. Nonetheless, we believe that the increasing assignment of well-trained sleep personnel distributed to various geographic areas may alleviate this limitation in the future. Secondly, we did not use a nasal pressure transducer

in the Home PSG. Therefore, it could not match perfectly with the in-Lab PSG, although similar definitions for scoring events were used. However, our reason is that we intended to use as minimal recording channels in Home PSG as possible which would be more comfortable to the patients and similar to the routine or real clinical practice. Thirdly, the computer software systems for analysis were different, which was also common for several studies, particularly on previous PM reports [14]. In this study, we used Grass Technology for Home PSG to reduce the cost of investigation instead of Compumedics system which was used in sleep laboratory. Nonetheless, it is unclear whether the application of different PSG systems will affect the interpretation of study results. Finally, we did not assess respiratory effort-related arousals and periodic leg movements during sleep because the high variability of inter-personal agreement in scoring of these events may reduce the reliability of the tests and made the comparison with other studies more difficult, particularly with the well-known SHHS [1, 4, 17] and Sleep AHEAD [20].

Conclusion

This is the first report of home-based diagnosis of OSA by PSG type 2 in Asia which demonstrated its excellent diagnostic properties compared to the gold standard. Home PSG can be reliably performed by experienced sleep personnel with a low failure rate and no serious adverse events. Its advantages over other sleep monitoring systems are that it provides information not only about respiratory-related parameters but also on other important sleep parameters that are almost similar to the gold standard in patients' most familiar environment. It also increases the accessibility of PSG at probably a lower cost for both research and clinical practice since it is not limited by the availability of laboratory beds and overnight attending staffs. Therefore, it should be considered as an interesting alternative method in diagnosis of OSA in an era of economic constraints. However, we recommended that patients with significant medical or sleep-related co-morbidities who are at risk for immediate therapeutic intervention are preferentially recorded in the in-Lab PSG. We also encourage that further studies should focus on the cost-effectiveness of Home PSG in order to optimize its use for sleep medicine practice in the future.

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Conflict of interest The authors declare that they have no conflict of interest.

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