Diagnostic accuracy and feasibility of portable sleep monitoring in patients with obstructive sleep apnea: Re-exploring the utility in the current COVID-19 pandemic

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Abstract

Portable sleep monitoring (PSM) is a promising alternative diagnostic tool for obstructive sleep apnea (OSA) especially in high burden resource limited settings. We aimed to determine the diagnostic accuracy and feasibility of PSM device-based studies in patients presenting for evaluation of OSA at a tertiary care hospital in North-India. PSM studies (using a type-III PSM device) were compared for technical reliability and diagnostic accuracy with the standard laboratory-based type-I polysomnography (PSG). Patients were also interviewed about their experience on undergoing an unsupervised PSM studies. Fifty patients (68% males) were enrolled in the study, of which only 30% patients expressed their concerns about undergoing unsupervised PSM studies which included safety issues, ease of use, diagnostic accuracy, etc. Technical acceptability criteria were easily met by the PSM studies with signal loss in 12% studies (complete data loss and inaccessible data in 6% studies), warranting repetition sleep studies in four patients. The overall sensitivity of PSM device (AHI ≥5) was 93.5% (area under curve; AUC: 0.87). The diagnostic accuracy was 68.5%, 80%, and 91.4% for mild, moderate, and severe cases of OSA, respectively. An overall strong correlation was observed between PSM-AHI (apnea-hypopnea index) and PSG ($r>0.85$, $p\leq0.001$), especially in severe OSA. The observed sensitivity was >90% for AHI>20 (clinically significant OSA), with high specificity of 91% for severe OSA (AUC: 0.94, 0.97 for AHI>20, AHI>30 respectively). The overall Bland-Altman concordance analysis also demonstrated only a small dispersion for PSM studies with a Cronbach's coefficient of 0.95. Therefore, there is good diagnostic accuracy as well as feasibility of home-based portable sleep studies in Indian patients. It can be promoted for widespread use in high burden countries like India for diagnosing and managing appropriately selected stable patients with high clinical probability of OSA, especially during the ongoing crises of COVID-19 pandemic.

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Introduction

Obstructive sleep apnea (OSA), a syndrome characterized by repeated episodes of upper airway obstruction during sleep, is a common disorder with significant morbidity and mortality. OSA is present in up to 15% of middle-aged adults, primarily in obese males [1,2]. It is currently estimated that 17% of men and 9% of women between the ages of 50 and 70 years have moderate-to-severe sleep disordered breathing (SDB) [3,4]. In fact, the prevalence could reach up to 40% among patients who snore or are obese, acromegalics, diabetic, or with craniofacial abnormalities [1-4]. OSA is increasingly being recognized as a major health burden due to rising awareness among patients as well as physicians about the disease [5]. Despite being a growing health concern with rising prevalence, it is estimated that most patients of OSA neither receive a diagnosis nor are treated. The Wisconsin Sleep Cohort

Study (WSCS) revealed that as high as 93% of women and 82% of men with moderate to severe OSA were under diagnosed [6].

The diagnosis of OSA is established through comprehensive sleep evaluation, which includes detailed history, thorough physical examination, and sleep testing i.e., polysomnography (PSG) [7]. Sleep studies are categorized into the following four types: type-I, standard PSG; type-II, comprehensive portable PSG; type-III, modified portable sleep apnea testing (e.g., respiratory polygraphy); and type-IV, continuous single-bio parameter or dual-bio parameter recording [8]. An overnight attended laboratory based PSG is considered to be the current 'gold standard' diagnostic test, against which other types of sleep monitors are compared [9]. However, type-I PSG is technically complex, labor intensive, and expensive. In addition, there is a scarcity of dedicated sleep laboratories with certified sleep specialists in developing countries like India.

Portable sleep monitoring (PSM) has recently captured the interest of physicians evaluating sleep apnea, because they have the potential to address the highly unmet need for diagnosis of OSA in high burden resource limited settings. PSM devices are used to obtain unattended recordings at home, specifically focusing on cardio-respiratory bio-parameters, making sleep testing widely available and seemingly more economical. Additional advantages include ease of use and the ability to record sleep in a natural environment [10]. Recently, there has been an increased interest in exploring, developing, and validating more cost-effective and patient friendly portable devices for diagnosing OSA [11-13].

The American Academy of Sleep Medicine (AASM) guidelines on the use of PSM devices have proposed their use in patients with high pre-test probability of OSA; for whom in-laboratory PSG is not possible by virtue of immobility, infirmity, inaccessibility, or critical illness; and in patients to monitor the response to non-CPAP treatments for sleep apnea [14]. Although PSM devices have been supported by the guidelines, most studies attempting to determine the accuracy of such devices have not followed standardized methodology for diagnostic test validation [15]. Moreover, no study has ever evaluated the real-world scenario on feasibility, validity and status of PSM studies in India. Therefore, there still appears to be a lot of lacunae in the existing knowledge about PSM devices especially from the developing world. Hence, the present study was planned to determine the accuracy of unattended Type-III PSM device-based study as compared to the laboratory-based Type I PSG. It also aimed to assess the feasibility of performing home based PSM device-based studies for the diagnosis of OSA in Indian patients.

Materials and Methods

A prospective study was conducted at the Department of Pulmonary, Critical care, and Sleep Medicine at Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, over a period of one year. The study was conducted after approval from the Institutional Ethics Committee. All consecutive, clinically stable adult patients (age ≥18 years) referred to the dedicated sleep clinic of our facility for evaluation of OSA, were screened for the study. Each patient was subjected to the Berlin [16] and Epworth Sleepiness Scale (ESS) survey questionnaires [17] for screening of sleep apnea. The patients were prospectively enrolled after obtaining a written, informed consent. Enrolled patients were provided with a detailed information about the two types of sleep studies i.e., a laboratory-based PSG and a home-based PSM device-based, and the study plan. At the baseline visit, details of their symptoms, and co-morbidities were recorded. All participants had their sleep and medical history collected, along with thorough physical examination including body mass index (BMI); neck and waist circumferences; etc. Eligible patients who consented for the study were assigned dates for their sleep studies after explaining that the sleep studies will be carried out twice, once in the laboratory (supervised type I study) followed by another one at home (unsupervised type III study), on two different nights and with a maximum interval of one week between two studies. These patients were also interviewed about their opinion and choice between undergoing type-I PSG study and home-based PSM device-based study.

Sleep studies

Over-night PSG studies

Patients underwent supervised full-night type-I PSG using Alice 6 Diagnostic Sleep System, (Philips Respironics, Inc., Monroeville, PA, USA) with a total of 55 channels and 19 dedicated EEG inputs**,** was carried out according to the AASM standard methodology [18,19]. The study was carried out in the designated, quiet, and comfortable sleep laboratory with ambient temperature maintained around 25-28°C.. These studies were conducted by an experienced sleep technician. The sensors were attached using-water soluble adhesives and gels with tape. All the signals and impedance values were checked prior to the study.

Portable sleep monitoring studies

PSM studies were performed with type III-PSM device - Stardust II Sleep Recorder (STD). It is based on the proven Alice 4 software; with windows-based application that is easy to learn and use. It is designed to measure and record 5 diagnostic parameters: spO_2 (*via* finger probe), pulse rate (from the oximeter probe), airflow (pressure-based airflow through a nasal cannula), respiratory effort (piezoelectric sensor in a belt placed mid-thorax), and body position (mercury switch built into the unit). An internal 9-V battery allows up to 10 h of data collection. The application procedure was demonstrated to the patients in detail, and the equipment was handed out to the patients, who were clearly instructed on its use to their satisfaction. The patients were told to remove the sensors on the next morning and return the equipment, so that the data stored in the internal memory could be read and interpreted manually using specific software.

After having undergone both types of sleep studies (PSG and PSM device-based), patients were again interviewed about their preference and experience regarding the two diagnostic modalities and their reasons to choose that diagnostic modality. The sleep data was reviewed and validated by two experienced sleep specialists independently. The studies were assessed for signal quality using SHHS criteria for acceptability and manually validated [20,21] The studies recorded using the PSM device, were considered failed if they lacked one or more of the following: 4 h of oximetry data, and/or 4 h of contiguous data from either abdominal, chest or nasal sensors. The sleep specialists scoring the studies were blinded to all the patient related information. The resulted were scored as per the AASM Manual of Scoring of Sleep and Associated Events [19].

Statistical analysis

Statistical analyses were performed using the SPSS statistical software, version 21.0 (SPSS Inc., Chicago, IL, USA).

Demographic and clinical (continuous) variables were presented with descriptive statistics (mean ± standard deviation). Data from PSG and respiratory parameters across the AHI values (log transformed) from the PSM-STD device were compared using the intra-subject ANOVA procedure. Pearson correlation coefficients were calculated for the dependent measures. Diagnostic accuracy of PSM was described by sensitivity, specificity, positive (PPV)/ negative predictive values (NPV), and positive/ negative likelihood ratio. Sensitivity, specificity, PPV, and NPV at AHI cut-off values of 5, 15, and 30 events/ hour were calculated using AHI values from PSG lab versus PSM. Using same series of comparisons, Receiver Operator Curves (ROCs) were constructed to illustrate true and false positive results. Bland-Altman plots were generated to assess agreement between PSG and PSM results. Similar calculations were also done for AHI cut-off value of >20, to assess for diagnosis of 'clinically significant OSA' by the two diagnostic modalities [22,23]. Concordance between PSM and PSG results was assessed by ROC curve analyses, intra-class correlation coefficient, and limits on the Bland-Altman plot. Bland-Altman concordance analysis was performed using the logarithmic transformation. A p-value of <0.05 and a probability of α error <5% have been considered as statistically significant.

Results

Clinico-demographic parameters

Consecutive adult patients presenting to our sleep clinic for evaluation of OSA were screened for the study, out of which, a total of fifty-five patients were found eligible for our study. Five of these patients had to be dropped from the study plan due to their socio-personal issues, and the remaining fifty patients were enrolled into the study (Figure 1). While all the enrolled patients underwent type-I PSG successfully, the overall drop-out rate from the PSM study group was 30% (15/50) for various reasons. Thirty-five patients finally completed both types of sleep studies. None of the enrolled patients were lost to follow-up.

The demographic and clinical profile of the enrolled patients (n=50) have been detailed in Table 1. With a mean age of 48.7 ± 10.7 years, more than two-thirds (68%) of our patients were males (M:F=2.12:1). The mean duration of symptoms prior to presentation was 4.4±2.3 years. The average scorings for sleepiness and clinically probability of OSA, using the Epworth Sleepiness Scale and Berlin Scores respectively were found to be clinically significant (15.66±4.92, and 2.5±0.5). The most common symptoms

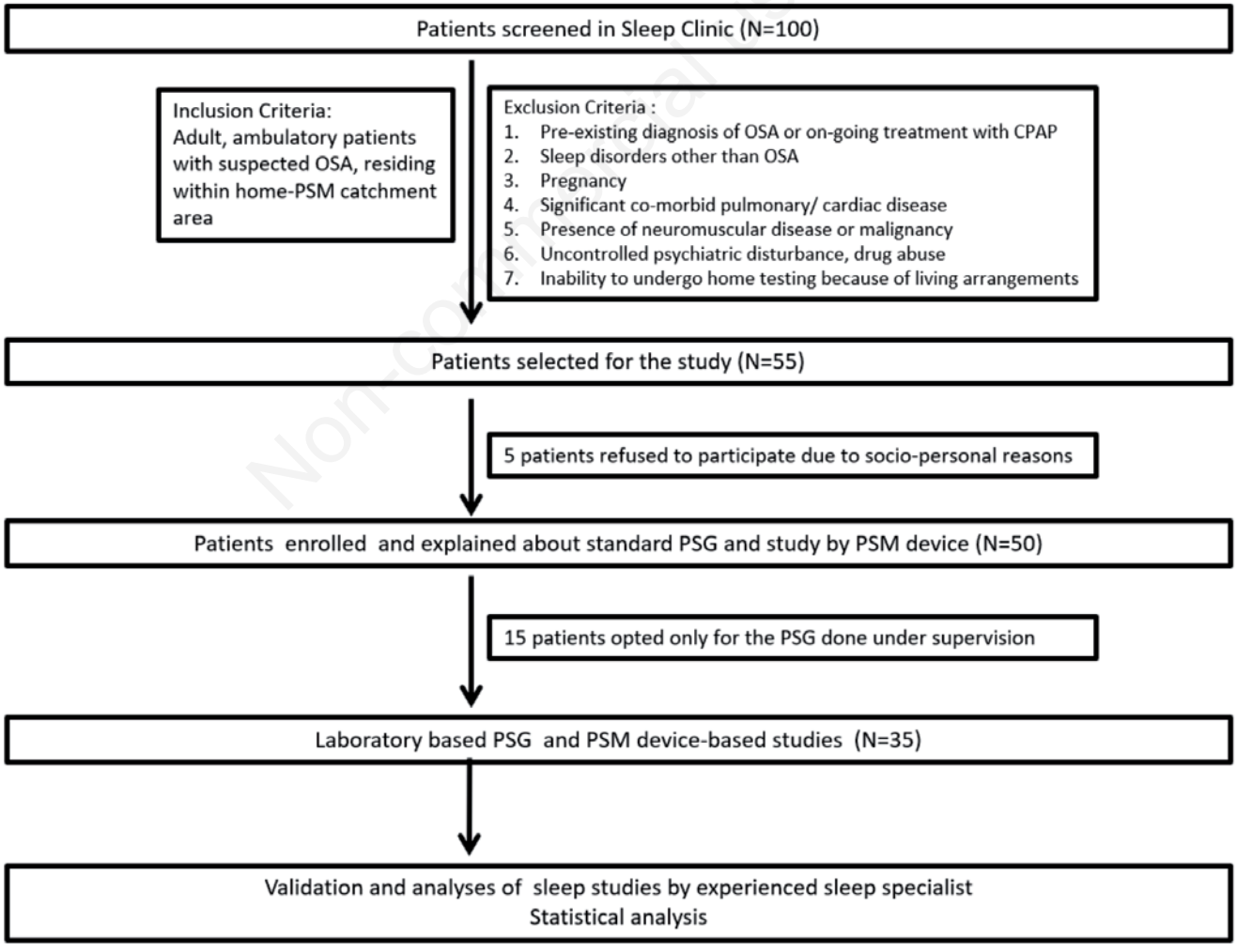

Figure 1. Study plan.

reported were excessive daytime sleepiness (100%); snoring (94.3%); easy fatigability (85.7%); restless sleep (71.4%); choking spells (68.6%); witnessed apnea (71.4%); unrefreshing sleep (60%); pathological nocturia (54.3%); poor memory (45.7%); sleepiness while driving (28.6%); palpitations and anxiety (28.6%); morning headaches (25.7%); insomnia (17.1%); anxiety (15%); etc. Some gender-specific differences were noted in the distribution of symptoms as well. While witnessed apneas were documented to be significantly more common in males (82.6% vs 50% in females; $p<0.05$); insomnia, and anxiety were seen more frequently in females. Patients were also documented to have stable comorbidities at the time of presentation. The most common comorbidities were obesity (BMI:31.6±4.9 kg/m^2), hypertension (82.9%), diabetes mellitus (45.7%), dyslipidemia (48.6%), and hypothyroidism (34.3%).

Table 1. Demographic and clinical profile of patients (n=50) (mean±standard deviation).

Demographic profile	
Age (years)	48.6±10.7
Males (n)	34 (68%)
Smoking history (n)	10 (20%)
Chronic alcohol abuse (n)	8 (16%)
Duration of symptoms (years)	4.4±2.3
Clinical findings	
Epworth Sleepiness Score (ESS)	15.66±4.92
Berlin score	2.5±0.5
BMI (kg/m2)	31.6± 4.94
WHR	1.02±0.07
Neck circumference (inches)	15.76±1.26
PR (/min)	90.94±6.96
SBP (mmHg)	137.83±11.45
DBP (mmHg)	88.29±6.58
sPO2 (% @ RA)	96.46±2.21
Laboratory investigations	
Hemoglobin (g/dl)	12.9±1.8
HBA1C (%)	6.8±2.0
Serum insulin (fasting) (µU/L)	11.2±2.5
Serum insulin (post prandial (µU/L)	32.8±12.6
Serum TSH (µIU/L)	2.65±0.52
Serum CRP (mg/L)	3.6±0.2
Serum triglycerides (mg/dl)	145.6±28.4
Serum LDL (mg/dl)	121.4±15.6
Arterial blood gas analysis	
pH	7.42±.02
pO_2 (mm Hg)	77.4±9.1
HCO_3 (meq/L)	21.5±2.0
Spirometry values	
FEV_1/FVC (%)	82.6±6.3
FVC (%)	85.3±10.8
FEV_1 (%)	81.3±11.4

ESS, Epworth Sleepiness Score; BMI, body mass index; WHR, waist hip ratio; PR, pulse rate; SBP, systolic blood pressure; DBP, diastolic blood pressure; RR, respiratory rate; sPO_2, saturation on pulse oximetry; HBA1C, glycated hemoglobin; TSH, thyroid stimulating hormone; C - reactive protein; LDL, low-density lipoprotein; pO_2, partial pressure of O_2; HCO_3, bicarbonate; FEV_1, forced expiratory volume in 1 sec; FVC, forced vital capacity.

Sleep study quality and parameters

The various parameters of sleep architecture in the enrolled patients have been shown in Table 2. The sleep architecture showed gross distortion with compromised REM sleep. Despite a good sleep efficiency (93±5.7%), patients had a disrupted sleep with WASO (wake after sleep onset) of 24.97±25.12 min. The data for the respiratory events as well as calculated AHI were analyzed and compared for both the modalities (Table 3). All the respiratory parameters had a significantly good correlation between the two types of sleep studies, except the hypopnea index ($p=0.119$). Also, number of desaturations and desaturation indices were significantly different between the two modalities ($p=0.037$; 0.003 respectively). The values for both still showed an overall good correlation. The mean AHI of the patients with PSG and PSM device were 33.11±28.61 and 34.67±28.77, respectively. It is worth reporting that females presented with less severe disease (AHIs between males and females; 47.33±28.48 and 15.22±15.49, respectively).

A strong correlation was observed between the overall PSG-AHI and PSM-AHI ($r=0.845$; $p<0.001$), as well as the AHI values by the two modalities between males and females (r (males)=0.887, r (females)=0.764; $p<0.05$).

The severity-wise analysis (mild, moderate, severe OSA) for correlation of AHI between PSG and PSM however, revealed poor correlation in the mild and moderate groups but a strong and significant correlation in the severe OSA group, as shown in Table 3.

Table 2. Sleep architecture and events (n=50).

TIB (min)	459.28±81.86
TST (min)	423.98±80.80
WBS/ sleep onset (min)	5.36±6.97
WASO (min)	24.97±25.12
REM sleep (min)	22.38±25.41
NREM (min)	401.02±80.48
SWS duration (min)	47.00±56.64
Sleep efficiency (TST/TIB *100)	93.11±5.68
REM %	5.14±5.72
N1 %	18.45±15.40
N2%	64.66±18.18
N3%	11.76±14.19
Respiratory event arousal Index	20.61±13.06
A+H arousal Index	14.38±12.95
RERA arousal Index	6.23±9.57
Total snoring episodes	377.77±278.03
Snoring % of TST	15.29±11.06
Total resp. events	235.34±222.48
Total AHI	33.11±28.61
REM AHI	15.66±27.93
NREM AHI	32.66±28.88
RERAI	5.01±8.45
Total RDI	38.01±27.14

TIB, time in bed; TST, total sleep time; WBS, wake before sleep; WASO, wake after sleep onset; REM, rapid eye movement; NREM, Non-rapid eye movement; SWS, slow wave sleep; A, apnea; H, hypopnea; RERA; respiratory effort related arousal; AHI, apnea hypopnea index; RDI, respiratory disturbance index.

The diagnostic accuracy of the PSM device was also determined in comparison to the standard PSG studies. The sensitivity, specificity; positive and negative predictive values (PPV, NPV); false positive rates and false negative rates (FPR, FNR); and area under ROC (AUC); were calculated for the PSM device-based studies as shown in Table 4 and Figure 2. The probability of PSM study to correctly diagnose OSA at AHI ≥5 was 93.55% with 6.45% FNR. The specificity also increased in direct relation with the increase in AHI cut-off value. The results suggested good overall accuracy of PSM as a diagnostic modality (85.7%; AUC 0.87) and the accuracy appeared to significantly increase at AHIs>20. The Bland-Altman concordance analysis demonstrated relatively small dispersion for PSM study and showed a strong agreement between the AHI values estimating the Cronbach's alpha value of 0.952 shown in Figure 3.

Technical problems were seen in only 25% of the PSM device recordings overall. Technical acceptability criteria were easily met by PSM device-based studies with signal loss in 12% of the studies (complete data loss and inaccessible data in 6% studies), warranting repetition of PSM studies in four patients.

Patient preference and acceptability

Study participants were interviewed regarding their preference on undergoing a supervised PSG and a home-based PSM study for the diagnosis of OSA. The overall drop-out rate from the PSM study group was 30% (15/50). These patients opted only for the gold standard diagnostic test i.e., PSG under supervision and showed reluctance in performing a home-based unsupervised test on their own. The remaining thirty-five patients who underwent both PSG as well as PSM study were also asked about their experience and preference regarding the two diagnostic modalities. While 80% patients preferred to have a PSM-device based study, only 5 patients (14.2%) preferred the PSG and 2 (5.8%) had no specific preference for any of the two diagnostic modalities. These

Table 3. Comparison of respiratory parameters and AHI (PSG *vs* PSM device-based sleep studies) (total n=35).

		Mean±standard deviation	p-value*	Correlation	p-value**
Total respiratory events	PSG PSM	235.34±222.48 223.60±212.30	0.870	0.820	0.000
AI (apnea index)	PSG PSM	21.82±24.61 24.77±25.63	0.266	0.888	0.000
HI (hypopnea index)	PSG PSM	11.29±9.50 9.89±6.71	0.376	0.268	0.119
Desaturation index	PSG PSM	24.529±26.85 30.55±29.64	0.003	0.927	0.000
Lowest spO2%	PSG PSM	75.63±19.76 76.63±14.134	0.568	0.868	0.000
Overall AHI	PSG PSM	33.11±28.61 34.67±28.77	0.688	0.845	0.000
AHI (<5)	PSG PSM	2.50±1.28 9.33±4.20	0.068	0.400	0.600
AHI (5-15)	PSG PSM	9.46±3.02 13.74±12.29	0.767	-0.183	0.637
AHI (15-30)	PSG PSM	21.05±3.82 22.59±9.97	0.998	-0.095	0.823
AHI (>30)	PSG PSM	63.95±18.39 62.26±24.57	0.594	0.886	0.000
Total AHI (males) (n=22)	PSG PSM	47.33±28.48 46.54±31.60	0.858	0.887	0.000
Total AHI (females) (n=13)	PSG PSM	15.22±15.49 18.25±12.40	0.249	0.764	0.002

*Wilcoxon test: used to test difference between two machine observations (data follow non-normal distribution); **Spearman's rank correlation coefficient calculated between two machine observations; p<0.05 has been taken as statistically significant.

Table 4. Diagnostic accuracy of PSM device based sleep studies as per disease severity (total n=35).

OSA classification (by PSG)	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)	False positive rate (%)	False negative rate (%)	Area under ROC curve
AHI ≥ 5 (All cases of OSA)	93.55	25	90.6	33.3	75	6.45	0.87
AHI ≥5-15 (Mild OSA)	44.44	76.9	40	80	23	55.5	0.69
AHI ≥15- ≤30 (Moderate OSA)	50	88.88	57.1	85.71	11.1	50	0.79
AHI >20 (Clinically significant OSA)	94.44	76.47	80.95	92.85	23.5	5.5	0.94
AHI >30 (Severe OSA)	92.98	90.48	56.67	95	9.52	7.11	0.97

findings suggestive of patient preferences and acceptability of PSM devices as a diagnostic modality in India have been tabulated (Table 5).

Discussion

There are various issues pertaining to the use of PSM devices for diagnosing and managing OSA in actual clinical practice; especially in high burden resource limited countries with socio-culturally diverse population, like India. This study has included not only the diagnostic accuracy of PSM devices laboratory-based PSG, but also highlighted the challenges faced during PSM studies in terms of patient acceptability and feasibility.

Firstly, we analyzed the diagnostic accuracy of PSM device (type III device) in comparison with the current gold standard PSG, in Indian population. Earlier, many non-inferiority trials [11,12,24-28] have compared home-based diagnostic sleep studies with in-laboratory PSG for the diagnosis of OSA. They have shown good diagnostic performance, in patients with high pre-test probability of moderate-to-severe OSAS, suggesting that unattend-

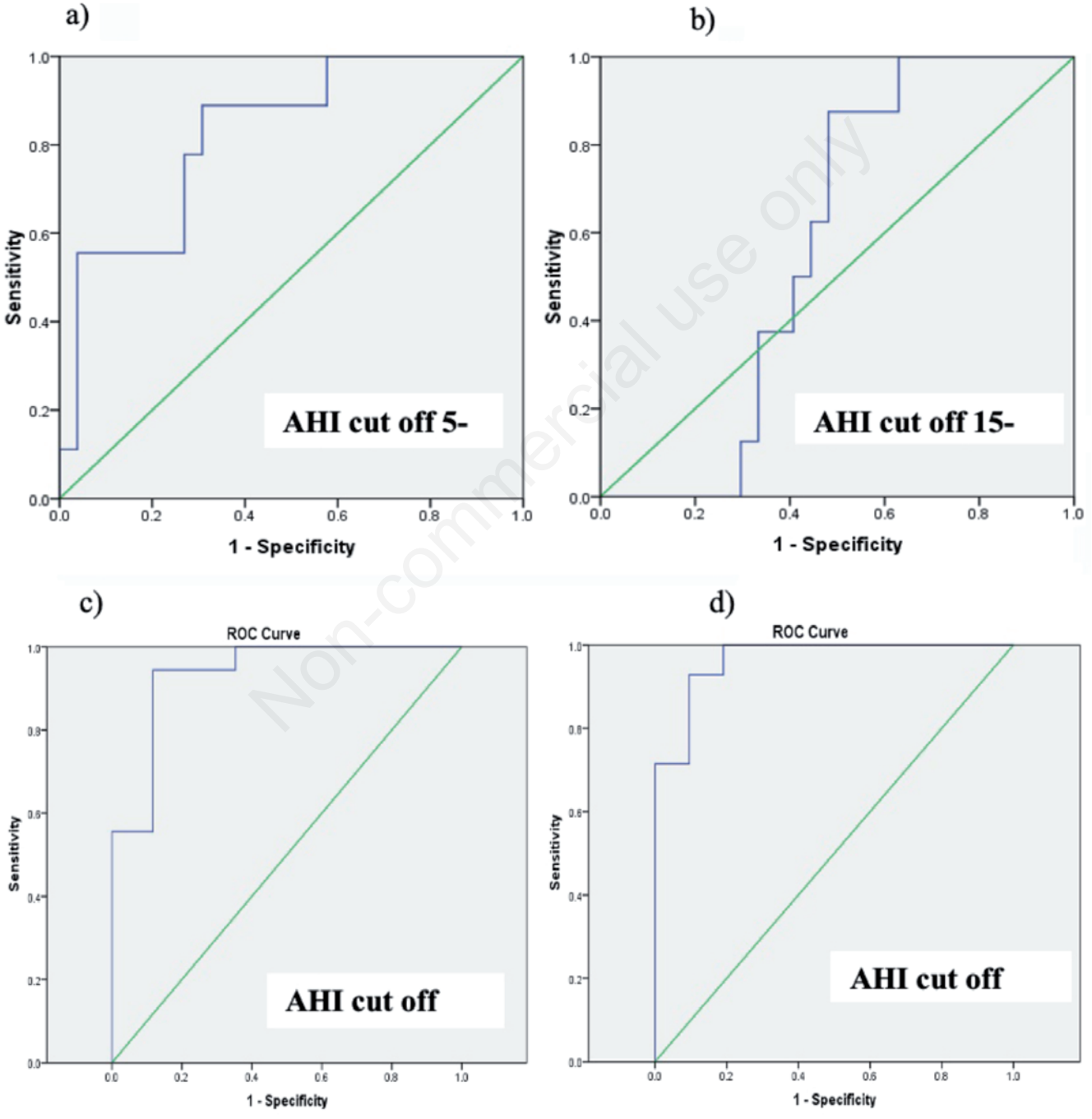

Figure 2. ROC curves at different AHI cut off.

ed diagnostic sleep study is a feasible alternative to laboratory-based PSG with a good concordance (>80% agreement). Some of these studies had specially focused on the use of type-III PSM devices [24-27] for diagnostic sleep studies. These studies concluded that PSM devices may be accurate in confirming the diagnosis of OSA where there is high index of suspicion for OSA (moderate to severe cases) [29]. In a recent meta-analysis by Shayeb *et al*. [15] that reviewed around 19 studies comparing PSG with type-III PSM devices, it was found that in patients with no unstable co-morbidities, the results of both type of sleep studies correlated well in moderate to severe OSA.

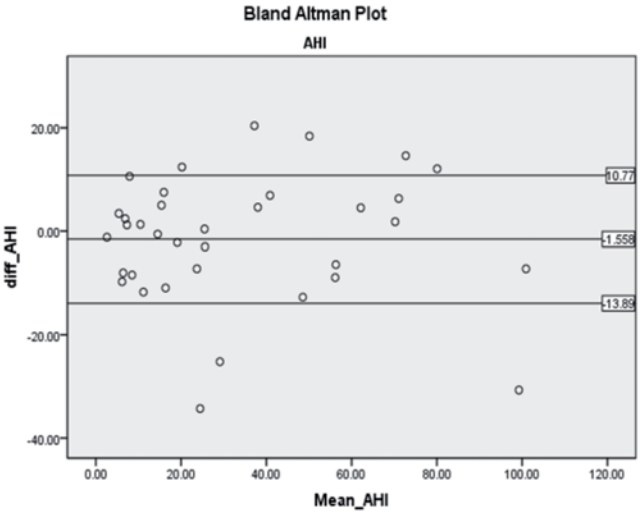

Figure 3. Bland Altman analysis between AHIs from PSG and PSM device sleep studies.

The results of our study agree with the currently available evidence in support of the use of type-III PSM devices for diagnosis of moderate to severe OSA. An earlier study by Ballester *et al*. [31] validated a home-based respiratory PSM device for general population with high level of agreement, showing a sensitivity and specificity of 95% and 92%, respectively. Similarly, in various other studies, the diagnostic agreement has been reported between 75% and 91% with multiple comparisons at AHI cut-off values of 5, 15, and 30 [24-27,31-33]. In our study, we found that the probability of PSM study to correctly diagnose OSA at AHI ≥5 was found to be quite good at a sensitivity value of 93.55%, with an area under the ROC (AUC) of 0.87. Therefore, with a sensitive AHI cut-off point of AHI≥5, PSM effectively includes all cases of OSA. In contrast to the findings of earlier studies reporting false negative rate (FNR) at 17% [34] with PSM devices, we found an overall FNR at 6.45%. The results suggest that overall accuracy of PSM device as diagnostic modality (85.7%) has a good correlation with PSG.

On the other hand, diagnostic accuracy also correlated well with increasing AHI also. At a cut-off of AHI≥30 (severe OSA), PSM device confirmed most of the cases with a sensitivity and specificity of 92.9% and 90.5% respectively. Although, moderate to severe OSA group remains clinically most relevant; mild OSA has been inadequately studied in earlier studies [24-33]. Despite high diagnostic accuracy for severe OSA, we failed to show a good sensitivity and specificity for mild to moderate OSA, which represent the latent burden of this disease as community health problem.

The previous evidence on unattended type-III PSM device-based studies reported data loss in the range of 3-18% while in attended settings, the range was around 3-9% [26,27]. A recent study from a resource limited setting [37] on quality of ambulatory

Table 5. Acceptability and feasibility of portable sleep studies.

Prior to the study (n=50)	
Patients opting only for PSG and not wanting to get an un-attended type III PSM study	15 (30%)
Reasons:	
a) Diagnosis by only gold standard test (PSG)	15
b) Possibility of more accurate diagnosis	15
c) Chances of getting repeat study after a PSM study	12
d) Difficulty in performing an unattended study	12
e) Safety issues while using PSM at home	12
Post-study findings (n=35)	
Home-based PSM study	
Experience:	
a) Easy to use, Ability to sleep in their bed with familiar and more comfortable environment	
b) Getting medical services at their doorstep through the PSM studies, Avoiding the much time-consuming visit to the sleep laboratory	
Preference to have the study done with a PSM device (n=35)	28 (80%)
Reasons:	
a) Cheaper diagnostic test	28
b) Ease of use	25
c) Lesser number of channels	20
d) Better sleep quality	18
e) Less time-consuming option	15
Preference to have a laboratory PSG (n=35)	5 (14.2%)
Reasons:	
a) Test done by a trained sleep technician	5
b) Most accurate diagnosis	5
No preference	2 (5.8%)

sleep monitoring, showed that while 57 (81%) met the definition of good quality study, 13 (19%) had to be repeated. In our study, we found signal loss in only 12% of the studies (with complete data loss and inaccessible data in 6% studies), warranting repetition of PSM studies in only four patients. There are various practical implications to high rate of signal failure and data loss with PSM devices; including delayed diagnosis, increase in the overall cost burden of sleep diagnostics, and unnecessary anxiety and frustration among patients requiring repetition of studies [38]. Recently to circumvent the issue of poor-quality data, Maestri *et al*. [39] have proposed computer assisted approach to quantitative assessment of portable sleep studies.

Another issue raised frequently by many practicing physicians is regarding the feasibility and patient acceptability of home-based PSM studies in a real-world scenario. In our study, the participants were interviewed regarding their acceptance and experience with the two different types of diagnostic sleep tests, both prior to as well as at the end of the study. To the best of our knowledge, this aspect of PSM device-based studies has not been explored earlier in any of the studies. Although this aspect has never been the primary focus, however, some studies did conclude that home-based strategy for diagnosis and treatment of OSA was not inferior in terms of acceptance, adherence, time to treatment, and functional improvements [30,34-36]. We have reported that the overall drop-out rate from the PSM study group was only 30%. Interestingly, we also found that Indian patients had reservations in undergoing home-based unsupervised studies since laboratory based supervised PSG could offer them an accurate diagnosis and potentially improvise their treatment decisions. Additional concerns expressed by the Indian patients include safety issues, additional cost burdens, unwanted loss of data, need for repetition of sleep study, wastage of time, etc. with the PSM studies at homes. Despite a good diagnostic accuracy of PSM device-based sleep studies in symptomatic moderate to severe OSA, challenges remain in its wide-spread utilization. Based on the findings of our study, it is evident that the socio-cultural and educational diversity of patients could be a pressing concern against the wide-spread use of PSM devices in many developing countries like India in terms of acceptance, adherence, and overall feasibility. Patient counselling and education regarding the PSM devices and their use in appropriately selected population must be adequately ensured.

The strength of our study is that it provides the real-world experience on the diagnostic accuracy and feasibility of performing the home-based PSM studies in OSA patients in developing countries like India. However, there were some limitations to our study. The study has been done on a small sample drawn from the symptomatic patients referred to our tertiary care hospital for evaluation of OSA; therefore, the generalizability of results from this group is limited. Secondly, several devices that fall under the denomination of PSM devices require individual validation against PSG since each of them records different numbers and types of bio-parameters. Thirdly, this study was not aimed to investigate the economic aspects and cost-effectiveness of PSM studies. These factors could additionally play an important role in deciding patient acceptability and overall feasibility of PSM studies in developing countries.

Conclusions

Even with increasing awareness, OSA continues to be an undiagnosed or misdiagnosed entity in various parts of the world. Despite being the gold standard test, access to supervised laboratory-based PSG remains limited in developing countries for various reasons. PSM devices with their excellent diagnostic accuracy in symptomatic moderate-severe OSA, are promising alternative diagnostic tools. The availability of well-validated PSM devices and their use in the hands of dedicated and trained sleep physicians may decrease the sole reliance on laboratory based PSGs for effectively managing cases with clinically significant OSA, especially in the times of ongoing COVID-19 pandemic. However, poor selection of cases coupled with an increased use of these devices in the hands of untrained professionals would worsen the problem of delaying or misdiagnosing simple OSA, and treatment of other sleep related breathing disorders like complex sleep apnea, upper airway resistance syndrome, sleep linked hypoventilation, etc. Large scale studies are still needed to determine and explore the feasibility, acceptability, and cost-effectiveness of portable sleep studies in India, especially in the milder phenotype of OSA.

References

1. Young T, Palta M, Dempsey J, et al. The occurrence of sleep disordered breathing among middle-aged adults. N Engl J Med 1993;328:1230–5.
2. Bixler EO, Vgontzas AN, Ten Have T, et al. Effects of age on sleep apnea in men: Prevalence and severity. Am J Respir Crit Care Med 1998;157:144-8.
3. Punjabi NM. The epidemiology of adult obstructive sleep apnea. Proc Am Thorac Soc 2008;5:136-43.
4. Hashim Z, Nath A, Gupta M, et al. Diagnosis of obstructive sleep apnea in women: Is there any difference? - Experience from a tertiary care hospital of North India. J Family Med Prim Care 2019;8:3276-81.
5. Peppard PE, Young T, Barent HG, et al. Increased prevalence of sleep disordered breathing in adults. Am J Epidemiol 2013;177:1006-9.
6. Young T, Palta M, Dempsey J, et al. Burden of sleep apnea: rationale, design, and major findings of the Wisconsin Sleep Cohort study. WMJ 2009;108:246-9.
7. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med 2017;13:479–504.
8. Polese JF, Santos-Silva R, Kobayashi RF, et al. Portable monitoring devices in the diagnosis of obstructive sleep apnea: current status, advantages, and limitations. J Bras Pneumol 2010;36:498-505.
9. Chesson AL Jr, Ferber RA, Fry JM, et al. The indications for polysomnography and related procedures. Sleep 1997;20: 423-487.
10. Collop NA, Tracy SL, Kapur V, et al. Obstructive sleep apnea devices for out-of-center (OOC) testing: technology evaluation. J Clin Sleep Med 2011;7:531-48.
11. Berry RB, Hill G, Thompson L, McLaurin V. Portable monitoring and autotitration versus polysomnography for the diagnosis and treatment of sleep apnea. Sleep 2008;31:1423-31.
12. Garg N, Rolle AJ, Lee TA, Prasad B. Home-based diagnosis of obstructive sleep apnea in an urban population. J Clin Sleep Med 2014;10:879885.
13. Krishnaswamy U, Aneja A, Kumar RM, Kumar TP. Utility of portable monitoring in the diagnosis of obstructive sleep apnea. J Postgrad Med 2015;61:223-9.

14. Collop NA, Anderson WM, Boehlecke B, et al. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. Portable Monitoring Task Force of the American Academy of Sleep Medicine. J Clin Sleep Med 2007;3:737-47.
15. El Shayeb M, Topfer LA, Stafinski T, et al. Diagnostic accuracy of level 3 portable sleep tests versus level 1 polysomnography for sleep-disordered breathing: a systematic review and meta-analysis. CMAJ 2014;186:E25–51.
16. Senaratna CV, Perret JL, Matheson MC, et al. Validity of the Berlin questionnaire in detecting obstructive sleep apnea: A systematic review and meta-analysis. Sleep Med Rev 2017;36:116124.
17. Chiu HY, Chen PY, Chuang LP, et al. Diagnostic accuracy of the Berlin questionnaire, STOP-BANG, STOP, and Epworth sleepiness scale in detecting obstructive sleep apnea: A bi-variate meta-analysis. Sleep Med Rev 2017;36:57-70.
18. Iber C, Ancoli-Israel S, Chesson A, Quan SF. The AASM manual for the scoring of sleep and associated events: rules, terminology and technical specifications. Westchester: American Academy of Sleep Medicine; 2007.
19. Berry RB, Brooks R, Gamaldo C, et al. AASM Scoring Manual Updates for 2017 (Version 2.4). J Clin Sleep Med 2017;13:665-6.
20. Iber C, Redline S, Kaplan Gilpin AM, et al. Polysomnography performed in the unattended home versus the attended laboratory setting – Sleep Heart Health Study methodology. Sleep 2004;27:536-40.
21. Kapur V, Rapoport D, Sanders M, et al. Rates of sensor loss in unattended home polysomnography: the influence of age, gender, obesity and sleep disordered breathing. Sleep 2000;23:682–8.
22. He J, Kryger MH, Zorick FJ, et al. Mortality and apnea index in obstructive sleep apnea. Experience in 385 male patients. Chest 1988;94:9-14.
23. Ge X, Han F, Huang Y, et al. Is obstructive sleep apnea associated with cardiovascular and all-cause mortality? PLoS One 2013;8:e69432.
24. Corral J, Sánchez-Quiroga MÁ, Carmona-Bernal C, et al. Conventional polysomnography is not necessary for the management of most patients with suspected obstructive sleep apnea. Noninferiority, randomized controlled trial. Am J Respir Crit Care Med 2017;196:1181-90.
25. Tonelli de Oliveira AC, Martinez D, Vasconcelos LF, et al. Diagnosis of obstructive sleep apnea syndrome and its outcomes with home portable monitoring. Chest 2009;135:330–3.
26. Santos-Silva R, Sartori DE, Truksinas V, et al. Validation of a portable monitoring system for the diagnosis of obstructive sleep apnea syndrome. Sleep 2009;32:629-36.
27. Skomro RP, Gjevre J, Reid J, et al. Outcomes of home-based diagnosis and treatment of obstructive sleep apnea. Chest 2010;138:257–63.
28. Campbell AJ, Neill AM. Home set-up polysomnography in the assessment of suspected obstructive sleep apnea. J Sleep Res 2011;20:207-13.
29. Aung K. In suspected OSA, home respiratory polygraphy was non-inferior to polysomnography for reducing symptoms. Ann Intern Med 2018;168:JC20.
30. Rosen CL, Auckley D, Benca R, et al. A multisite randomized trial of portable sleep studies and positive airway pressure auto titration versus laboratory-based PSG for diagnosis and treatment of obstructive sleep apnea: The Home PAP Study. Sleep 2012;35:757-67.
31. Ballester E, Solans M, Vila X, et al. Evaluation of a portable respiratory recording device for detecting apnoeas and hypopnoeas in subjects from a general population. Eur Respir J 2000;16:123-7.
32. Us S, Baroody FM, Kohrman M, Suskind D. A comparison of polysomnography and a portable home sleep study in the diagnosis of obstructive sleep apnea syndrome. Otolaryngol Head Neck Surg 2004;131 844-50.
33. Reichert JA, Bloch DA, Cundiff E, et al. Comparison of the NovaSom QSG, a new sleep apnea home-diagnostic system, and polysomnography. Sleep Med 2003;4:213–8.
34. Berry RB, Sriram P. Auto-adjusting positive airway pressure treatment for sleep apnea diagnosed by home sleeps testing. J Clin Sleep Med 2014;10:1269–75.
35. Garg N, Rolle AJ, Lee TA, et al. Home-based diagnosis of obstructive sleep apnea in an urban population. J Clin Sleep Med 2014;10:879–85.
36. Masa JF, Corral J, Sanchez de Cos J, et al. Effectiveness of three sleep apnea management alternatives. Sleep 2013;36:1799-807.
37. Hernández-Bendezú MDC, Arias-Peña MY, Torres-Fraga MG, Carrillo-Alduenda JL. Quality of an ambulatory monitoring technique for diagnosing obstructive sleep apnea under conditions of limited resources. Sleep Sci 2018;11:269-73.
38. Gay PC, Selecky PA. Are sleep studies appropriately done in the home? Respir Care 2010;55:66-73.
39. Maestri R, Robbi E, Lovagnini M, et al. Quantitative assessment of the quality of home sleep studies: A computer-assisted approach. J Sleep Res 2020;29:e12899.