ORIGINAL ARTICLE



Comparative study of the SleepImage ring device and polysomnography for diagnosing obstructive sleep apnea

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Abstract

Purpose We aim to evaluate the diagnostic performance of the SleepImage Ring device in identifying obstructive sleep apnea (OSA) across different severity in comparison to standard polysomnography (PSG). *Methods* Thirty-nine patients (mean age, 56.8 ± 15.0 years; 29 [74.3%] males) were measured with the SleepImage Ring and PSG study simultaneously in order to evaluate the diagnostic performance of the SleepImage device for diagnosing OSA. Variables such as sensitivity, specificity, positive and negative likelihood ratio, positive and negative predictive value, and accuracy were calculated with PSG-AHI thresholds of 5, 15, and 30 events/h. Receiver operating characteristic curves were also built according to the above PSG-AHI thresholds. In addition, we analyzed the correlation and agreement between the apnea-hypopnea index (AHI) obtained from the two measurement devices. *Results* There was a strong correlation (r=0.89, *P*<0.001 and high agreement in AHI between the SleepImage Ring and standard PSG. Also, the SleepImage Ring showed reliable diagnostic capability, with areas under the receiver operating characteristic curve of 1.00 (95% CI, 0.91, 1.00), 0.90 (95% CI, 0.77, 0.97), and 0.98 (95% CI, 0.88, 1.000) for corresponding PSG-AHI of 5, 15 and 30 events/h, respectively. *Conclusion* The SleepImage Ring could be a clinically reliable and cheaper alternative to the gold standard PSG when aiming to diagnose OSA in adults.

Keywords Apnea-hypopnea index · Cardiopulmonary coupling · Polysomnography · Obstructive sleep apnea

1 Introduction

Obstructive sleep apnea (OSA) is a clinical condition characterized by repetitive collapse of the upper airway during sleep. Nearly 1 billion people worldwide are estimated to have OSA, and it is likely to increase with the ageing population and ongoing obesity epidemic [1–3]. According to a recent population-based cohort study, almost half of the population in northeast Germany suffers from OSA [4]. Untreated OSA is associated with an increased likelihood

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of comorbidities, such as hypertension, heart disease, and stroke [5, 6]. However, only about 20% of patients have been diagnosed and treated, suggesting a massive diagnosis and treatment gap [7].

To date, overnight in-laboratory polysomnography (PSG) remains the gold standard for diagnosing OSA [8]; nevertheless, disadvantages such as technical complexity, laborintensive procedures, long waiting times, and high costs limit its general availability [9]. Furthermore, patients may find the PSG device to be uncomfortable due to the multiple electrodes that are required to be attached to the face, head, and body in an unfamiliar environment for accurate measurement, which will lead to the first-night effect [10, 11]. In this case, multiple nights of recording are recommended, however, it is not practical. As a result, many portable and cheaper devices have been developed to address these issues.

Among varied devices, the cardiopulmonary coupling (CPC) technique-based portable device has been increasing in interest among researchers and physicians. The CPC technique calculates the coherence between heart/pulse rate variability and respiratory excursion derived

from a single-lead electrocardiogram (ECG) or photoplethysmogram (PPG) to generate distinct CPC patterns [12, 13]. Elevated low-frequency coupling (e-LFC) was discovered to be one of the characteristic patterns substantially linked with apnea and hypopnea [14]. Therefore, the new SleepImage Ring device uses the PPG sensor to collect both the Plethysmogram (PLETH) and the oxygen saturation (SpO_2) signals. From here, the device can calculate the apnea-hypopnea index (sAHI) by combining the CPC parameters and hypoxic events. Al Ashry and his colleagues analyzed the ECG and oximetry data on PSG from the database of Apnea Positive Pressure Long-term Efficacy Study and calculated the sAHI value. They found there was a strong correlation between sAHI and manually scored PSG-AHI [15]. However, there are no studies that directly validate the diagnostic performance of the portable monitoring device-SleepImage Ring for diagnosing adult OSA. We hypothesized the sAHI derived from SleepImage Ring would have a high agreement with the AHI of nurse-attended PSG in assessing OSA severity. Therefore, we aim to evaluate the diagnostic value of the SleepImage Ring device compared with PSG in identifying OSA in adults.

2 Materials and methods

2.1 Procedure and participants

This prospective study protocol was approved by the Ethics Committee of Charité University Medicine Berlin (EA1/093/22). Written informed consent was obtained from all participants.

Consecutive patients aged ≥ 18 years referred to the Interdisciplinary Sleep Medicine Center of Charité University Medicine Berlin for further assessment of sleep apnea between August 2022 and February 2023 were eligible for this study. The exclusion criteria were as follows: (1) finger problems related to the inability to use SleepImage Ring devices; (2) patients who do not have a mobile phone and/or cannot download the accompanying App; (3) patients with severe cognitive impairment who cannot understand how to use the device; (4) patients with previously diagnosed severe sleep disorders other than sleep apnea; (5) the SleepImage report is unavailable due to test failure.

Investigators interviewed patients for their demographic, clinical, and health behavior-related characteristics (e.g., age, sex, height, weight, smoking status, comorbidities, etc.) in a quiet setting. In addition, since some patients have been diagnosed with OSA by preliminary tests such as polygraphy, they also provided the results of their latest sleep test.

2.2 Polysomnography

All participants underwent a full-night in-laboratory PSG at the sleep center. The standard PSG examination included frontal, central, and occipital electroencephalogram, electrooculogram, chin electromyogram, tibialis anterior electromyogram, ECG, respiratory airflow (thermistor and pressure transducer), thoracic-abdominal effort (respiratory inductance plethysmography), SpO₂, snoring, and body position. The recorded data were scored manually by experienced sleep technicians according to the American Academy of Sleep Medicine (AASM) manual for the Interpretation of Sleep and Related Events [11]. Apnea was defined as an airflow drop $\geq 90\%$ of the preevent baseline for at least 10 s. Hypopnea was defined as when the airflow drops by $\geq 30\%$ for at least 10 s in association with either $\geq 3\%$ oxygen desaturation or arousal. Apnea-hypopnea index (AHI) was calculated as the average number of apnea and hypopnea events per hour of sleep. According to AHI, the severity of OSA was classified as follows: mild: $5 \le AHI < 15$ events/h, moderate: $15 \le AHI < 30$ events/h, and severe ≥ 30 events/h.

2.3 SleepImage Ring

Patients wore the SleepImage Ring device whilst undergoing the PSG study. The SleepImage Ring system comprises a finger-worn recorder (Fig. 1a), a SleepImage Mobile App with a secure cloud-based portal (Fig. 1b). The Ring recorder, equipped with a PPG sensor, was used to collect PLETH and SpO₂ data signals, while the mobile App was used to data transfer. The cloud-based SleepImage system (MyCardio LLC, Denver, CO, USA) automatically analyzed the coherence and cross-spectral power of pulse rate variability and respiration derived from PLETH using the CPC technique. By combining CPC data with SpO₂ data, the SleepImage Ring-based AHI (sAHI) is calculated. The analytical methods of the CPC technique were described in detail previously [12]. Also, the SleepImage system complies with the EU Medical Device Directive (CE mark 0413).

The process from monitoring to report generation involved the following steps: (1) place the thumb or index finger in the Ring recorder; (2) pair the Ring recorder with the SleepImage App using Bluetooth; (3) Click the play button on the App to start a recording before going to sleep; (4) press the stop button to end the study and upload the recording; (5) generate the sleep report automatically in the system. Figure 2 shows the final sleep report and spectrogram. **Fig. 1** Schematic of the Sleep-Image Ring device. **a** shows the finger-worn recorder, and **b** shows the SleepImage Mobile App



2.4 Sample size calculation

According to our study hypothesis, we used the kappa test for agreement between two raters to calculate the sample size (PASS version 15.0). The primary endpoint is the presence of OSA diagnosed by PSG. According to a previous study by Seo et al. [16], a sample size of 32 subjects achieves 80% power with a significance level of 0.05 to obtain a true kappa value of 0.70.

2.5 Statistical analysis

Categorical variables are presented as frequency (percentage) and continuous variables as mean ± standard deviation or median (interquartile range), as appropriate. To evaluate the diagnostic performance of the SleepImage Ring device, we calculated the sensitivity, specificity, positive and negative predictive value, positive and negative likelihood ratio, accuracy, and Youden index with PSG-AHI thresholds of 5, 15, and 30 events/h. The Youden index (sensitivity plus specificity minus 1) was used to determine the optimal cutoff values. Receiver operating characteristic (ROC) curves were also built according to the above PSG-AHI thresholds. In addition, to assess the agreement of the AHI between the SleepImage Ring device and PSG, we utilized paired *t*-tests and Bland-Altman analysis. Scatterplot was created to assess the correlation between the AHI and sAHI, and the Spearman correlation coefficient was calculated due to the skewed distribution of AHI. We used the Kendall *tau-b* to measure

the concordance of OSA severity assessed by the two methods. A value of P < 0.05 was considered statistically significant. The statistical analysis was performed using SPSS software (IBM SPSS Statistics, IBM Corporation). Figures were generated using GraphPad Prism version 9.0.

3 Results

3.1 Participants

A total of 39 participants (74.4% male) completed the PSG and SleepImage Ring study. Their mean age was 56.8 ± 15.0 years (range, 27–83 years), mean body mass index (BMI) was $30.8.0 \pm 7.2$ kg/m². The percentage of obesity (BMI \geq 30 kg/m2) was 46.2% (18/39). According to the PSG results, 14 patients (35.9%) had mild OSA, 6 (15.4%) had moderate OSA, and 17 (43.6%) had severe OSA. Their median (IQR) AHI and median (IQR) lowest SpO₂ were 22.4 (13.1, 56.9) events/h and 82.0 (73.0, 86.0) %, respectively. Characteristics of the participants are summarized in Table 1.

3.2 Correlation and agreement of AHI derived from two methods

There was a significantly positive correlation between the sAHI generated by SleepImage Ring and AHI obtained from PSG (Spearman correlation coefficient = 0.89,

sleep	Sleep Qua Aug 15, 2022 1 Interdisciplinary Universitätsmee	ality Report .0:47 PM - 5:48 AM Sleep Medicine Center lizin Berlin	r at Charit	é-			
	Sleep Quality			Sleep Opportunity			
SQI 40 Expected >55		EFFICIENCY 94% Expected >85%		LATENCY 0h:14m		DURATION 6h:45m	
				Expected <30 m	nin	Expecte	d 7-9 hours
	Sleep A	pnea		Sleep Pathol			,
sAHI	4% 47	sAHI _{3%} 62 Severe		FRAGMENTATION 19% Expected <15%		PERIODICITY 3% Expected ≤2%	
Se	vere						
Signal hh:mm 23:00	00:00	01:00	02:00	03:00	04:00		05:00
STABLE 4	12% - 2h:46m CVHF	R 31% sAHI3% 39					Expected >5
UNSTABL	.E 32% - 2h:08m CVHF	R 91% sAHI <mark>3</mark> % 87					Expected <3
REM 25%	- 1h:40m CVHF	7 <mark>9% sAHI3% 66</mark>					
						Desatu	irations
	Sleep Onset	11:02 PM				3%	4%
	TST	6h:34m		SAHIORSTRU		60	46
	WASO	0h:10m		SAHI _{CENTRAL}		2	1
WAKE TRANSITIONS		#4		sRDI		62	49
	SAI	49		ODI		58	43
	SpO ₂ <90%	0h:41m - 10%					
	SpO ₂ <88%	0h:17m - 4%				Min Mi	ax Mean
	SpO ₂ <80%	0m:51s - 0%			ON (sec)	10 4	7 18
MIN-N	MAX-MEAN SpO ₂	/0% - 98% - 92%		HEART RATE	(ВРМ)	54 10	<u>70</u>
Test Summary	/:						
Patient:	: 39 year old Ma	ale					
Average Signal Quality is 96 %. Sleep Quality is below expected value.			Sleep Apnea Indicator is above expected value. Apnea Hypopnea Index is Severe .				

Sleep Efficiency is **above** expected value. Sleep Duration is **not within** expected value. Sleep Apnea Indicator is **above** expected value Apnea Hypopnea Index is **Severe**. Sleep Fragmentation is **above** expected value. Periodicity is **above** expected value.



b

Published Notes:

There are no published notes

Spectrogram:





P < 0.001), along with a strong linear relationship (Fig. 3). Also, no significant difference was observed between the sAHI and AHI (30.2 ± 23.0 versus 32.9 ± 26.9 , P = 0.350). The Bland-Altman plot was used to estimate agreements between the sAHI and AHI (Fig. 4), reporting a mean difference of 2.7, and the 95% limit of agreement from -19 to 24, with 94.9% (37/39) observations in the limits of agreement. Table 2 shows the concordance of OSA severity assessed by the SleepImage Ring and PSG. We found

Table 1 Demographic characteristics of participants

Variables	Participants (N=39)		
Age, years	56.8 ± 15.0		
Male: Female	29: 10		
Height, cm	174.9 ± 8.0		
Weight, kg	94.0 ± 21.2		
BMI, kg/m2	30.8 ± 7.2		
AHI, /h	22.4 (13.1, 56.9)		
Total sleep time, min	364.8 ± 69.8		
Sleep efficiency, %	84.5 (69.0, 91.6)		
Lowest SpO ₂	82.0 (73.0, 86.0)		

Values are presented as mean \pm standard deviation or median (IQR) for continuous variables. AHI, apnea-hypopnea index, BMI, body mass index, SpO₂, oxygen saturation



Fig. 3 Scatterplot diagram showing the correlation between the sAHI and AHI (Spearman correlation coefficient = 0.90, P < 0.001). AHI, apnea -hypopnea index; sAHI, SleepImage apnea-hypopnea index



Fig.4 Bland-Altman plot for the level of agreement between the sAHI and AHI. AHI, apnea -hypopnea index; sAHI, SleepImage apnea-hypopnea index

significantly high concordance in OSA severity between the two methods (Kendall tau-b = 0.75, P < 0.001).

3.3 Diagnostic accuracy evaluation

Table 3 shows the sensitivity, specificity, false-positive rate, false-negative rate, positive predictive value, negative predictive value, positive likelihood ratio, negative likelihood ratio, accuracy, Cohen's kappa, and Youden index of the SleepImage Ring in diagnosing OSA at the PSG-AHI thresholds of 5, 15, and 30, respectively. The SleepImage Ring is accurate in detecting OSA (AHI \geq 5) with 100% sensitivity and 100% specificity. High accuracy was also demonstrated at other two PSG-AHI thresholds: 79% (95% CI 67%, 92%) for AHI \geq 15 and 90% (95% CI 80%, 99%) for AHI \geq 30, respectively. ROC curves were conducted to evaluate the diagnostic ability of the SleepImage Ring (Fig. 5). When the AHI > 5 events/h was set as the criteria to diagnose OSA, the area under the curve (AUC) was 1.00 (95% CI, 0.91, 1.00), the optimal cutoff value of sAHI was 4, the sensitivity and specificity were both 100%. When the AHI > 15 events/h was set as the criteria to diagnose OSA, the AUC was 0.90 (95% CI 0.77, 0.97), the optimal sAHI cutoff value was 16, the sensitivity and specificity were 87% and 81%, respectively. When an AHI of \geq 30 events/h was set as the criterion for diagnosing OSA, the AUC was 0.98 (95% CI, 0.88, 1.000), an sAHI value of 17 was optimal, yielding a sensitivity of 100% and specificity of 86%.

3.4 Previous polygraphy results for reference

Of these 39 patients, 32 also provided the results of their latest polygraphy tests, and the interval between the polygraphy study and PSG was from 20 days to 18 months. Twelve patients had a time interval of less than 3 months. The Spearman correlation coefficient of AHI between polygraphy and PSG was 0.57 (P < 0.001) whereas the Spearman correlation coefficient between the SleepImage Ring and PSG was 0.91 (P < 0.001) among these 32 patients. When the diagnostic standard was set as PSG-AHI \geq 15 events/ hour, the AUCs of SleepImage Ring and polygraphy were 0.938 and 0.78, respectively (Supplementary). The difference between areas was 0.15 (P = 0.08).

4 Discussion

This study indicates a high level of agreement and a significantly positive correlation between the sAHI obtained from the SleepImage Ring and the AHI from in-laboratory PSG. Additionally, we also found that the SleepImage Ring had a significant sensitivity, specificity, and agreement compared with PSG in both identifying the presence of OSA and categorizing its severity. These results suggest that the
 Table 2
 Concordance of OSA

 severity measured by two
 methods

Same severity = 71.8%. Kendall *tau-b* = 0.75 (P < 0.001). OSA, obstructive sleep apnea

Table 3DiagnosticPerformance of the SleepimageRing with polysomnography(N = 39)

Variable	Values (95% CI)					
	$\overline{\text{AHI} \ge 5 (\text{N} = 37)}$	$AHI \ge 15 (N = 23)$	$AHI \ge 30 (N = 17)$			
Sensitivity	1.00 (1.00, 1.00)	0.87 (0.73, 1.00)	0.88 (0.73, 1.00)			
Specificity	1.00 (1.00, 1.00)	0.69 (0.46, 0.91)	0.91 (0.79, 1.00)			
False-positive rate	0.00 (0.00, 0.00)	0.31 (0.09, 0.54)	0.09 (0.00, 0.21)			
False-negative rate	0.00 (0.00, 0.00)	0.13 (0.00, 0.27)	0.12 (0.00, 0.27)			
Positive likelihood ratio	NA	2.78 (1.32, 5.85)	9.71 (2.56, 36.80)			
Negative likelihood ratio	NA	0.19 (0.06, 0.57)	0.13 (0.03, 0.48)			
Positive predictive value	1.00 (1.00, 1.00)	0.80 (0.64, 0.96)	0.88 (0.73, 1.00)			
Negative predictive value	1.00 (1.00, 1.00)	0.79 (0.57, 1.00)	0.91 (0.79, 1.00)			
Accuracy	1.00 (1.00, 1.00)	0.79 (0.67, 0.92)	0.90 (0.80, 0.99)			
Youden index	1.00 (1.00, 1.00)	0.56 (0.29, 0.82)	0.79 (0.60, 0.99)			
Optimal cut-off value	4	16	17			

NPV, Negative predictive value; PPV, Positive predictive value; LR+, Positive likelihood ratio; LR-, Negative likelihood ratio



Fig. 5 ROC curve of diagnostic accuracy of the SleepImage Ring compared with standard polysomnography. **a** ROC curve for OSA diagnosis using $AHI \ge 5$ events/h as the threshold; **b** ROC curve for OSA using $AHI \ge 15$ events/h as the threshold; **c** ROC curve for OSA

using $AHI \ge 30$ events/h as the threshold. AHI, apnea -hypopnea index; sAHI, SleepImage apnea-hypopnea index; OSA, obstructive sleep apnea; ROC, receiver operating characteristic

SleepImage Ring could potentially be a great alternative diagnostic tool for OSA.

Since the CPC analysis was proposed by Thomas et al. in 2005, extensive clinical studies have evaluated its feasibility and accuracy in identifying OSA [17–20]. One of the validation studies was conducted by Lu et al. [20] in China, they assessed one portable device based on the CPC technique, and suggested the overall performance of this device was acceptable with the AUCs being 0.79, 0.79, and 0.86 across different OSA severity (mild, moderate, and severe). However, the device they used extracted signals from a single-lead ECG and generated AHI using

the e-LFC pattern. There are two subsets in the e-LFC spectrum: narrow-band (an indicator of periodicity) and broad-band (an indicator of fragmentation) e-LFC spectra. Other causes of sleep fragmentation (e.g., fibromyalgia, depression) can produce similar patterns and thus may affect the accuracy of the AHI [21, 22]. To reduce the aforementioned limitations, a new AHI calculation method that combines SpO₂ fluctuations with CPC data was proposed. Al Ashry et al. [15] analyzed ECG and pulse-oximeter tracings on PSG from a prospective clinical trial and generated the derived-AHI using the SleepImage system. The derived-AHI was validated to be comparable with the manual scoring AHI of PSG and approved by FDA both in adults and children [15, 23]. The SleepImage Ring, a new generation portable sleep monitoring device, could compute an AHI based on CPC-oximetry output from a PPG sensor and offer clinical users access to raw data, however, it has yet to be validated in a clinical context. To our knowledge, this is the first study to evaluate the diagnostic performance of the SleepImage Ring in identifying

OSA and categorizing its severity. In this study, we found a strong correlation and high agreement between the sAHI and the manually scored PSG-AHI, which is in line with the results of the technology validation study and furtherly affirms the feasibility of the SleepImage Ring in assessing OSA. We observed from the Bland-Altman plot that there is a significant difference between the AHI and sAHI in two patients (96.5 events/hour vs. 59.0 events/hour and 88.3 events/hour vs. 53.0 events/ hour, respectively). Fortunately, all values indicated severe OSA, so this difference has a relatively minimal impact on clinical diagnosis and subsequent treatment. Regarding the performance testing, although both sensitivity and specificity of the SleepImage Ring are 100% in diagnosing OSA $(AHI \ge 5)$, only 2 patients had an AHI of less than 5 in the current study. Therefore, the false positive rate needs to be interpreted with caution. In other words, it is difficult to achieve the conclusion that this portable device can accurately rule out non-OSA patients. When we set $AHI \ge 15$ events/h as criteria, the sensitivity, and specificity of the SleepImage Ring were 87% and 69%, respectively. The corresponding false-positive rate and false-negative rate were somewhat high with a total of 8 subjects categorized incorrectly. We, therefore, compared the AHI values obtained by the two methods of these eight patients and observed that the absolute difference (sAHI, AHI) between the two measures was within 0.18-3.4 events/hour in 4 of these patients. In addition, we found the optimal cutoff value of the SleepImage Ring in detecting patients with moderate-severe OSA is 16, with unchanged sensitivity (87%) and increased specificity (81%). The SleepImage Ring had a relatively high sensitivity (88%), specificity (91%), and accuracy (90%) in diagnosing severe OSA.

We also performed a comparison of ROC curves for the SleepImage Ring and polygraphy, both with PSG-AHI \geq 15 events/h as the classification variable. It appears that the SleepImgae Ring has better diagnostic performance than polygraphy, although the differences between regions are insignificant. Considering that the time interval between polygraphy and PSG testing is relatively large, where the time interval exceeds 3 months in the vast majority (62.5%) of patients, the results of the comparison are merely for reference.

Recently, there is a growing abundance of wearable sleeptracking devices. Relative to PSG and level 3 polygraphs, these consumer sleep trackers are easy-to-use, inexpensive, and low-burden. Among them, WatchPAT is a wrist-worn wearable device that utilizes the peripheral arterial signal for OSA diagnosis [24]. However, it is a single-use product, so it cannot be used once again. In comparison to other PPGbased ring devices, the SleepImage Ring showed commendable overall performance: Circul Ring (87% sensitivity, 83% specificity, and 0.929 AUC with PSG-AHI≥5 events/hour as threshold) [25], Belun Ring (95% sensitivity, 29% specificity, and 0.934 AUC with PSG-AHI > 5 events/hour as threshold)[26], Morpheus Ox (80% sensitivity, 86% specificity, and 0.909 AUC with PSG-AHI≥5 events/hour as threshold) [27]. SLEEPON Go2Sleep Ring can also monitor the severity of OSA; however, no validation study has been found yet. Another very well-known sleep-tracking ring in the Western world is the Oura Ring. Note that Oura Ring is not qualified for the medical diagnosis of sleep apnea. In contrast, the SleepImage Ring enables patients to record multiple nights of sleep in a natural sleep environment with high accuracy, thereby optimizing the management of sleep apnea.

This study has several limitations. First, the sample size is relatively small, especially the sample with an AHI of less than 5 events/h. As such, the clinical question regarding whether the SleepImage Ring can accurately rule out non-OSA patient needs to be explored in a larger population. Second, this study is limited by selection bias. All participants were recruited from the ward of the hospital sleep center. While most of the patients who came to the ward for PSG examination had already been screened for OSA using level 3 portable monitoring devices in the outpatient and wanted to seek further diagnosis and treatment. Third, we did not validate the performance of the SleepImage Ring in the home context where it is meant to be utilized. Fourth, the first-night effect of PSG may disturb sleep and affect signal quality. Finally, the failure rate of the SleepImage Ring test in the current study is relatively high. The likely reason is that most of our participants are elderly patients and may not be very good at using smartphones. We propose to add the option of data uploads for consumers, such as transferring data using data cables, which may effectively ensure data records.

5 Conclusions

In summary, the sAHI obtained from the SleepImage Ring had a high agreement with AHI from in-laboratory PSG in assessing the presence and severity of OSA. Therefore, the SleepImage Ring has the potential to be a clinically reliable tool and cheaper alternative to the gold standard PSG when aiming to diagnose OSA in adults.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s13534-023-00304-9.

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Declarations

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

Ethical approval This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of Charité University Medicine Berlin (EA1/093/22).

Consent to participate Informed consent was obtained from all individual participants included in the study.

Consent to publish The authors affirm that human research participants provided informed consent for publication of the images in Figure(s) 1 and 2.

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