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Diagnosis of obstructive sleep apnea using a bio-radar contact-free system compared with an established HST device in older adults

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ABSTRACT

Goal and aims: To compare a bio-radar contact-free monitoring device in diagnosing obstructive sleep apnea (OSA) in older people with an established home sleep apnea testing system (HST).
Focus method/technology: A bio-radar contact-free monitoring device (OrbSense+).
Reference method/technology: An established HST, Alice NightOne.
Sample: Fifty-three out of 63 recruited subjects were included in the final analysis. Seventy-two percent were male (age 72 ± 9 years; body mass index 31.05 ± 5.56 kg/m^2).
Design: An observational, prospective study.
Core analytics: Intraclass correlation coefficient (ICC), Bland-Altman analysis, and receiver operating characteristic analysis.
Additional analytics and exploratory analyses: None.
Core outcomes: Both 45 (84.91%) were diagnosed with OSA by Alice NightOne (average respiratory event index = 21.23 events/h) and by OrbSense+ (average respiratory event index = 25.98 events/h). Respiratory event index and oxygen desaturation index obtained by Alice NightOne and OrbSense+ were highly correlated, with ICC of 0.93 and 0.88, respectively. The Bland-Altman plot comparing the means showed good agreement between the 2 diagnostic techniques. With more than 5 respiratory events per hour as the standard for OSA diagnosis, OrbSense+ had a sensitivity of 100% and a specificity of 100% in diagnosis of OSA ($P <$ .0001). With more than 15 respiratory events per hour as the standard for OSA diagnosis, OrbSense+ was found to have a sensitivity of 100% and a specificity of 86.96% in diagnosis of OSA ($P <$ .0001).
Important additional outcomes: None.
Core conclusion: The bio-radar sleep monitoring device is a reasonably accurate home sleep apnea test for use in older patients.

Introduction

Rationale

As the gold standard for obstructive sleep apnea (OSA) diagnosis, laboratory-based polysomnography is not available in many health care facilities due to equipment cost and insufficient staffing.

Significance

A new and effective contact-free home sleep apnea test devices for OSA diagnosis for the older population is needed.

Background

OSA, a common sleep breathing disorder, is characterized by the occurrence, during sleep, of cyclic episodes of complete or partial obstruction of the upper airways, affecting 936 million individuals aged 30-69 years worldwide.[1] The prevalence of OSA increases with age.[2] OSA is associated with increased motor vehicle accidents,

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cardiovascular and cerebrovascular diseases,[3,4] metabolic disorders,[5] and cancers.[6]

As the gold standard for OSA diagnosis, laboratory-based polysomnography is not available in many health care facilities due to equipment cost and insufficient staffing.[2,7] With the development of home sleep apnea testing (portable monitoring technology) and relate evidence supporting the home based for OSA, home sleep apnea test devices have been recommended and are used for diagnosing of OSA in uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA.[8-11] However, some patients, especially old adults may not have normal sleep when using home sleep apnea test systems with numerous sensors on their body, and system and sensor failure occur and often cannot be detected and resolved in a timely manner. Thus, there is a need for new and effective contact-free home sleep apnea test devices for the older population.

Contact-free devices are desirable due to their low disruption of sleep and real-time monitoring capability. Bio-radar contact-free devices have been validated for OSA diagnosis.[12,13]

Aims

We evaluated a new home sleep apnea test, a bio-radar contact-free monitoring device (OrbSense+) for the diagnosis of OSA in older adults and compared it with an established home sleep apnea test system, a portable monitoring device (PM, Alice NightOne).

Methods

Sample

During July 2021 to December 2021, 63 people age ≥60 years with snoring and suspected OSA were recruited from the sleep center of Liqun Hospital, Shanghai, China. Patients with unstable medical conditions, such as severe respiratory failure, severe heart failure, and inability to complete the sleep detection were excluded. The study was approved by the Ethics Committee of Liqun Hospital (RT201912). All subjects received detailed information about the study, and informed consent was obtained.

Focus method/technology

The new bio-radar contact-free monitoring device (OrbSense+, Megahealth Medical, Inc, Zhejiang, China), uses an ultra-wideband wireless radar system to provide a contact-free radar sleep monitoring, integrating radar, and biomedical engineering technologies. OrbSense+ consists of 2 components: a radar-transmitting host for tracking respiratory movements and body movements wirelessly, and a finger plethysmograph (ie, "CIRCUL") for oxygen saturation monitoring[12-14] (Fig. 1). The radar monitoring device was placed within 2 m of the patient, with the antenna inside the device pointed toward the patient's chest, and the CIRCUL was worn on the index, middle, or ring finger. The patient is free to change body position during monitoring. OrbSense+ can distinguish whether the patient is in the bed and changes in body position, and can detect and remove wake time data. OrbSense+ processes all signals automatically with signal processing algorithms and generates a report, including total sleep time, respiratory event index (REI), oxygen desaturation index, total number of respiratory events, mean oxygen saturation ($MSaO_2$, %), and lowest oxygen saturation ($LSaO_2$, %).[12,15]

Reference method/technology

An established portable monitoring device (PM), the Alice NightOne (Philips-Respironics, Inc, Murrysville, PA) system was used to record signals that included nasal airflow, chest and abdominal movements and pulse oximetry. The result of the PM was analyzed automatically by analysis software, and then manually interpreted again. Total number of respiratory events, REI, oxygen desaturation index, mean oxygen saturation (MSaO2, %), and lowest oxygen saturation (LSaO2, %) were calculated.

Design, study setting, and procedures

All patients were monitored with the OrbSense+ device and PM simultaneously in the sleep center of Liqun Hospital. We defined apnea as the complete cessation of respiratory flow for over 10 seconds, and hypopnea as a reduction in respiratory flow lasting for over 10 seconds and accompanied by oxygen desaturation of at least 3%. A REI cutoff of ≥5 events/h combined with clinical symptoms were used to define OSA. Further, the severity was classified as mild OSA ($5 \geq REI < 15$), moderate OSA ($15 \geq REI < 30$), or severe OSA ($REI \geq 30$). All results were manually interpreted by 2 certified physicians according to the criteria in "*The AASM Manual for the Scoring of Sleep and Associated Events*."[8] If the results were different, a third physician was invited to interpret the results.

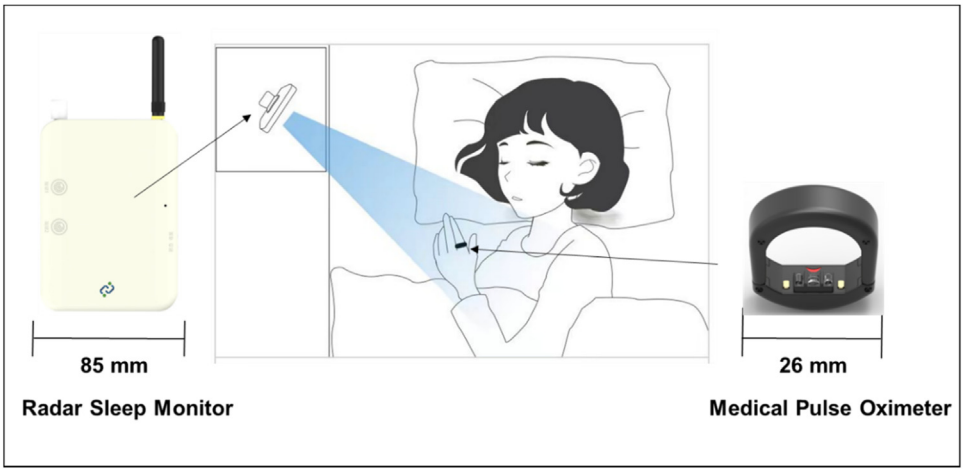

Fig. 1. New bio-radar contact-free monitor device. New bio-radar contact-free monitor (OrbSense+), consists of 2 components, a radar transmitting host for tracking respiratory and body movement, and a ring for oxygen saturation monitoring (pulse oximeter).

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Core analytics and main outcome variables

Measurement data were presented as means ± standard deviation, and count data were presented as percentages (%). Agreement sleep events between the 2 diagnostic methods on sleep event were assessed using the nonparametric Wilcoxon signed-rank test. Intraclass correlation coefficients (ICC) and Bland-Altman tests were used to evaluate the agreement on REI and oxygen desaturation index from the 2 techniques. Diagnostic accuracy of OrbSense+ to discriminate OSA was quantified by sensitivity and specificity. Statistical analyses were performed using SPSS version 22.0 (SPSS Inc, Chicago, IL). $P < .05$ was considered statistically significant.

Additional analytics and exploratory analyses

None.

Results

Core analytics and main outcome variables

Demographics

The study screened a total of 63 subjects, who were all monitored with both OrbSense+ device and PM simultaneously. Ten patients were excluded because of over 2 hours without any record of breath wave or SpO2 (7 patients for PM and 3 patients for OrbSense+). Finally, 53 cases (male 71.69%, mean body mass index 30.05 ± 5.56 kg/m^2, mean age 72 ± 9 years) were included in the analysis. OSA was diagnosed by PM in a total of 45 patients (84.91%) with an average REI of 21.23 events per hour. Of them, 15 patients (28.30%) had mild OSA, 16 patients (30.19%) had moderate OSA, and 14 patients (26.42%) had severe OSA. By OrbSense+, 45 patients (84.91%) met the criteria for a diagnosis of OSA, with an average REI of 25.98 events per hour, including 5 mild, 25 moderate, and 15 severe OSA, respectively (Table 1).

Correlation and Bland-Altman analysis

The total number of respiratory events determined by OrbSense+ (161.38 ± 126.99) was not significantly different by PM (159.30 ± 130.73), $P = .199$. The recording time (in minutes) by OrbSense+ (379.98 ± 69.66) was shorter than that by PM (445.88 ± 78.48), $P < .001$, as OrbSense+ removed awake time using signal processing algorithms, which may contribute to higher REI and oxygen desaturation index obtained by OrbSense+ (vs. PM: 25.98 ± 18.64 vs. 21.23 ± 16.46, $P = .000$, and 21.93 ± 17.16 vs. 18.44 ± 16.67, $P = .001$, respectively; Table 2).

A good degree of agreement and reliability in the ICC was observed between 2 methods. REI and oxygen desaturation index obtained from PM and OrbSense+ were highly correlated with ICCs, as shown in Table 2 and Fig. 2. The Bland-Altman analysis revealed a high level of agreement between PM and OrbSense+ (mean bias: −4.8 events/h of REI, 95% confidence interval [CI]: −14.5 to 5.0 events/h; mean bias of −3.5 events/h of oxygen desaturation index, 95% CI: −18.9 to 11.9 events/h). Fifty-one of 53 (96.23%) points for REI and 52/53 (98.11%) points for oxygen desaturation index located within the limits of agreement and its 95% CI, which means a high agreement between both REI and oxygen desaturation index from PM and OrbSense+ (Fig. 3).

Receiver operating characteristic analysis

With more than 5 respiratory events per hour as the standard for OSA diagnosis, OrbSense+ had a sensitivity of 100% and a specificity of 100% in diagnosis of OSA ($P < .0001$). With more than 15 respiratory events per hour as the standard for OSA diagnosis, OrbSense+ was found to have a sensitivity of 100% and a specificity of 86.96% in diagnosis of OSA ($P < .0001$). The area under the receiver operating characteristic (ROC) curve was used to compare the diagnostic validity of OrbSense+ vs. PM for the

Table 1
The sleep parameters and obstructive sleep apnea severity obtained from 2 devices (n = 53)

	Number of patients, n (%) n = 53		REI, mean ± SD n = 53		ODI, mean ± SD n = 53	
	PM	OrbSense+	PM	OrbSense+	PM	OrbSense+
No OSA	8 (15.09)	8 (15.09)	1.86 ± 1.25	2.69 ± 1.52	1.41 ± 1.28	4.25 ± 2.22
Mild OSA	15 (28.30)	5 (9.43)	9.69 ± 2.50	10.34 ± 1.45	7.80 ± 5.66	9.30 ± 0.92
Moderate OSA	16 (30.19)	25 (47.17)	21.59 ± 3.89	21.83 ± 5.24	18.85 ± 6.97	19.52 ± 7.96
Severe OSA	14 (26.42)	15 (28.30)	44.25 ± 10.19	50.55 ± 12.92	39.11 ± 15.81	39.59 ± 20.04
Total	53 (100)	53 (100)	21.23 ± 16.46	25.98 ± 18.64	18.44 ± 16.67	21.93 ± 17.16

PM, portable monitoring (Alice NightOne); SD, standard deviation; REI, respiratory event index; ODI, oxygen desaturation index; OSA, obstructive sleep apnea.

Table 2
Comparison of sleep parameters obtained using PM and OrbSense+

	PM	OrbSense+	P^a	Coefficient	P^b	R^c	P^c
Number of patients	53	53					
Total sleep time	445.88 ± 78.48	379.98 ± 69.66	.000	0.57	.000	0.79	<.01
Total events	159.30 ± 130.73	161.38 ± 126.99	.199	0.97	.000	0.97	<.01
REI	21.23 ± 16.46	25.98 ± 18.64	.000	0.93	.000	0.97	<.01
ODI	18.44 ± 16.67	21.93 ± 17.16	.001	0.88	.000	0.89	<.01

PM, portable monitoring (Alice NightOne); REI, respiratory event index; ODI, oxygen desaturation index.
Values are presented as mean ± standard deviation.
[a] Aanlysis by Wilcoxon signed-rank test.
[b] Intraclass correlation coefficients of PM vs. OrbSense+: 2-way random model assessing absolute agreement, for single measures.
[c] P values were estimated by the Pearson correlation analysis.

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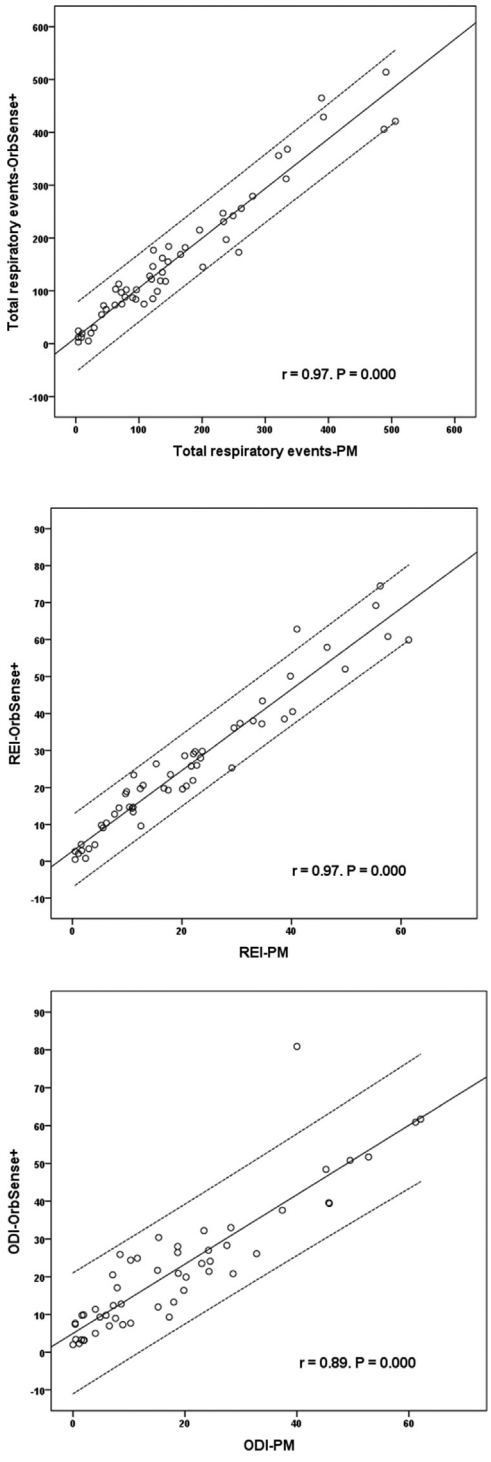

Fig. 2. Correlation analysis. Plots of total respiratory events, respiratory event index and oxygen desaturation index detected by PM and OrbSense+. Each point represents the results of one subject. The solid lines are the lines of identity. *P* values were estimated by the Pearson correlation analysis. REI, apnea-hypopnea index; ODI, oxygen desaturation index; PM, portable monitoring (Alice NightOne).

different cutoff points for OSA diagnosis. The values for the diagnosis of OSA were 1.000 (REI ≥5 events/h) and 0.984 (REI ≥15 events/h), respectively (Table 3, Fig. 4).

Additional analytics and exploratory analyses

None.

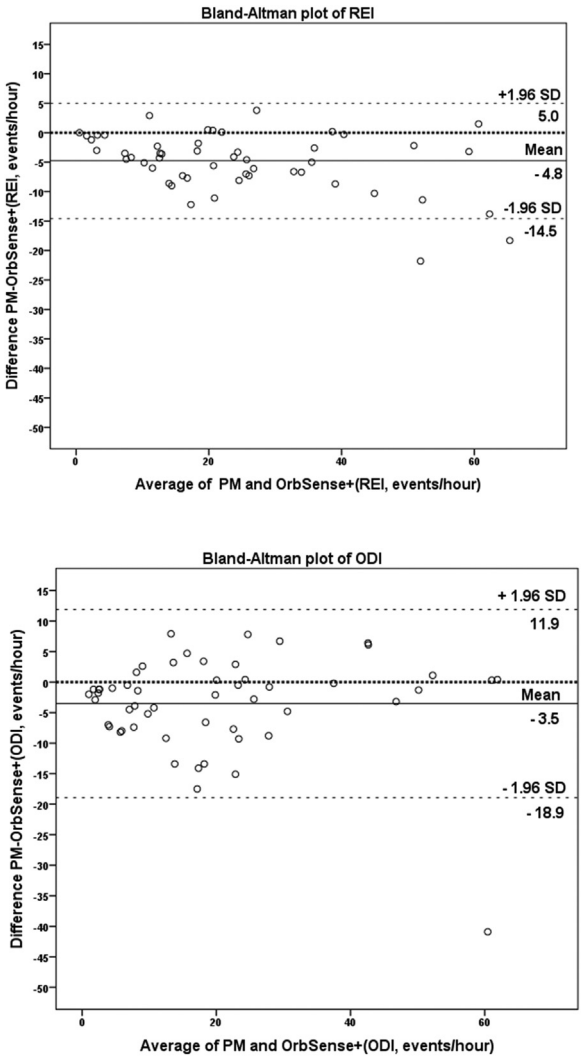

Fig. 3. Bland-Altman analysis. Bland-Altman plots of respiratory event index and oxygen desaturation index with the difference between potable PM and OrbSense+ measures plotted against the average of the 2 values. The solid line indicates the mean difference. The dashed lines show the 95% confidence intervals (CI). Fifty-one of 53 (96.23%) points for respiratory event index and 52/53 (98.11%) points for oxygen desaturation index located within the limits of agreement and its 95% CI, which means a high agreement between both respiratory event index and oxygen desaturation index from PM and OrbSense+. REI, respiratory event index; ODI, oxygen desaturation index; PM, portable monitoring (Alice NightOne).

Table 3
Diagnostic validity of OrbSense+

	REI ≥ 5	REI ≥ 15
Sensitivity	100%	100%
Specificity	100%	86.96%
Area under the curve	1.0	0.984
Best cutoff point (events/h)	6.85	19.10

REI, respiratory event index.

Discussion

Main results and implications

Worldwide, about one billion individuals are affected by OSA worldwide; however, most cases of OSA remain undiagnosed and untreated, even in developed countries.[16] The "gold standard" diagnostic test is laboratory-based polysomnography, which is

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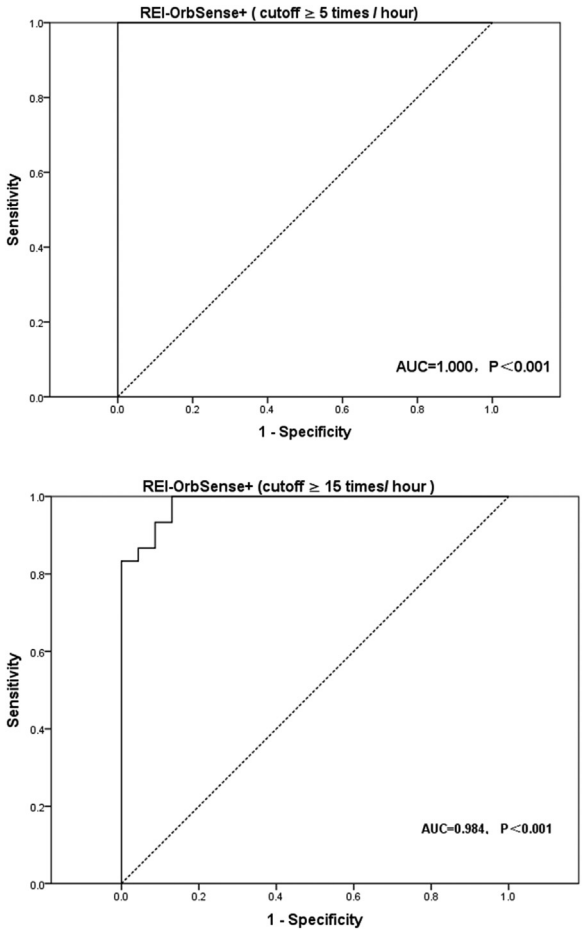

Fig. 4. ROC analysis. Receiver operating characteristic plot using respiratory event index (REI) PM cutoff of 5 events/h and 15 events/h to determine sensitivity and specificity for OrbSense+ values. The values of OrbSense+ for the diagnosis of obstructive sleep apnea were 1.000 (REI-PM ≥ 5 events/h) and 0.984 (REI-PM ≥ 15 events/h), respectively. PM, portable monitoring (Alice NightOne).

labor-intensive and inconvenient for the patient. Portable monitoring has been proposed as a reasonable substitute for in-laboratory polysomnography in most patients, except for those with severe cardiopulmonary or neuromuscular diseases.[13,17] In recent years, portable sleep monitoring devices using contact or contact-free sensor technology at home have greatly reduced barriers to diagnosis and facilitated routine management of OSA. In addition, portable monitoring enabled continued testing during the coronavirus disease 2019 pandemic.[18] Furthermore, contact-free devices used at home may show greater value due to their low less disruption of intervention on sleep, especially for older adults, who may not sleep normally in a hospital bed with numerous sensors on their body.

OrbSense+, a contact-free sleep test device, has been used in the screening and diagnosis of OSA.[15,17] Our study compared the effectiveness of OrbSense+ with an established portable monitoring device (Alice NightOne) in older adults. The failure rate of OrbSense+ and PM was about 4.8% and 11.1%, respectively, which was similar to other portable monitoring devices.[19] Fifty-three out of 63 recruited subjects were included in the final analysis. Forty-five (84.91%) were diagnosed with OSA by portable monitoring device (average REI = 21.23 events/h); similarly, 45 patients (84.91%) were diagnosed with OSA by OrbSense+ (average REI = 25.98 events/h). REI and oxygen desaturation index obtained by portable monitoring device and OrbSense+ were highly correlated, with ICC of 0.93 and 0.88, respectively. The Bland-Altman plot comparing the means showed good agreement between the 2 diagnostic techniques. As showed in Fig. 2, 2 cases for REI and 1 case for oxygen desaturation index showed significant difference between the 2 methods, but the difference did not affect diagnosis or the identification of the degree of severity. ROC analysis showed OrbSense+ had a high sensitivity and specificity in diagnosis of OSA; the values for the diagnosis of OSA were 1.000 (REI ≥5 events/h) and 0.984 (REI ≥15 events/h), respectively. In summary, our results suggested that contact-free monitoring can be useful in diagnosing older patients suspected of having OSA.

Additional results and implications

None.

Limitations and future perspectives

This study has several limitations. First, the small sample size may result in statistical bias. In the real world, diagnosis of OSA in older adults may be affected by confounding factors, especially the potential coexistence of chronic diseases (eg, chronic obstructive pulmonary disease, heart failure), which may need further investigation. Second, although OrbSense+ processes all the signals using signal processing algorithms, which can remove awake time and calculate total sleep time, no study has demonstrated the accuracy and the agreement between total sleep time as detected by bio-radar contact-free sleep monitoring vs. laboratory-based polysomnography; therefore, REI instead of apnea hypopnea index was used in this paper. Third, OrbSense+ currently can record only one night of data indicating a need for further development. Fourth, another limitation of the study is that the accuracy of the OrbSense+ was tested against only one type of portable monitoring device and the results may not generalize to other portable monitoring devices or to PSG.

Core conclusion

In conclusion, a bio-radar contact-free sleep monitoring device with a finger plethysmograph enabled diagnosis and evaluation of the severity of OSA in older adult. This device is promising for in clinical diagnosis, treatment follow-up, and population-based epidemiologic studies of OSA.

Declaration of conflict of interest

The authors have no conflicts to declare.

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Data sharing statement

No additional data are available.

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