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ORIGINAL RESEARCH

Diagnostic Accuracy of the Alice NightOne Single-Belt Monitor for Obstructive Sleep Apnea and Reliability of Wireless Data Transfer

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Objective: To validate the performance of a single-belt type 3 portable monitor Alice NightOne for diagnosis of obstructive sleep apnea and its reliability in remote data transmission.

Methods: Our study included two parts: in-laboratory Alice NightOne (ANO) monitoring (ANO_{lab}) and home sleep apnea testing (HSAT) using ANO (ANO_{home}). For ANO_{lab}, the participants underwent polysomnography (PSG) with ANO_{lab} simultaneously. For ANO_{home}, the participants completed unattended overnight ANO_{home} out of sleep center and PSG was performed in another night. The ANO recordings were transmitted to cloud database wirelessly in addition to traditional wire transmission. Message digest-5 (MD5) algorithm was utilized to verify the integrity of the cloud data.

Results: Ninety-one ANO_{lab} and 170 ANO_{home} recordings were analyzed. Both the respiratory event index (REI) on ANO_{lab} and that on ANO_{home} were lower than the corresponding apnea-hypopnea index (AHI) on PSG (24.9 ± 20.5 events/h vs 31.6 ± 25.0 events/h, and 26.7 ± 17.0 events/h vs 35.3 ± 21.2 events/h respectively, $P < 0.001$). Bland-Altman analysis of REI on ANO_{lab} versus AHI on PSG showed a mean difference (95% confidence interval) of −6.7 (−8.4, −4.9) events/h. For REI on ANO_{home} versus AHI on PSG, the difference is −8.0 (−9.9, −6.0) events/h. With threshold of REI ≥ 5 events/h for OSA diagnosis, ANO_{home} had 98.8% sensitivity, 90.0% specificity, 99.4% positive predictive value. The MD5 algorithm verified the identity between uploaded cloud data and original data.

Conclusion: With single thoracoabdominal belt, Alice NightOne can help diagnosis of obstructive sleep apnea with good sensitivity and specificity, though it may underestimate AHI. Furthermore, it provides reliable support based on solid data teletransmission and scoring synchronization, which may increase the ability of diagnosis and management of OSA through telemedicine.

Keywords: home sleep apnea testing, portable monitor, obstructive sleep apnea, telemedicine

Introduction

Since its development, polysomnography (PSG) has been the gold standard for diagnosis of obstructive sleep apnea (OSA). However, type 3 home sleep apnea testing (HSAT) was recommended for the diagnosis of moderate-to-severe OSA,[1–4] because of its convenience for remote patients, lower cost, and its critical role in telemedicine, particularly during the COVID-19 pandemic and other unique circumstances.[5–7] Current technology evaluation guidelines recommend the use of either two piezoelectric belts or respiratory inductance plethysmography (RIP) belts to assess respiratory effort due to insufficient evidence supporting the reliability of single-belt devices. Alice NightOne (ANO; Philips Respironics, Pittsburgh, Pennsylvania, USA) was identified as a type 3 portable monitor (PM), or $S_0C_4O_{1x}P_2E_2R_2$ device in SCOPER classification system, with only one thoracoabdominal RIP belt worn at the level of chest.[8,9] One objective of the present study was to validate the ANO monitor in a larger cohort and to evaluate its performance out of sleep center. By validating the performance of this single-belt PM, it may provide more evidence for respiratory effort assessment in HSAT guideline modifications.

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Telemedicine has been accepted rapidly with advances in information technology, particularly during the COVID-19 pandemic.[10] Despite this progress, there were very few studies published about the technology of HSAT data tele-transmission. ANO offers a platform enabling patients to upload HSAT recording data, technicians to access and score the data, and physicians to view detailed signal graphs and sleep reports, with its integrated sleep monitoring and scoring software. Accordingly, another objective of this study was to assess the reliability of ANO's remote data transmission capabilities.

Method

Participants

Patients aged 18 to 80 years who were referred to the Department of Sleep Medicine at Peking University People's Hospital with suspected OSA, such as those with symptoms of snoring, were enrolled in the study. Individuals with any of the following conditions were excluded: prior diagnosis of sleep disorders (eg central sleep apnea, obesity hypoventilation syndrome, narcolepsy, and rapid eye movement behavior disorder), severe cardiopulmonary diseases or unstable medical conditions (eg chronic obstructive pulmonary disease, heart failure, myocardial infarction, acute infection, trauma and surgery within one month), disturbed sleep regularity (shift work, jet lag or irregular work schedules over the past 1 month) or other contradictions for HSAT (eg neuromuscular diseases, opiate use, and insomnia). For sample size estimation, see Supplementary Material.

Protocol

Our study comprised two monitoring components: in-laboratory ANO monitoring (ANO_{lab}) and HSAT using ANO (ANO_{home}). For ANO_{lab}, participants underwent PSG and ANO monitoring simultaneously in the sleep laboratory. For ANO_{home}, patients underwent ANO_{home} out of sleep center, referring to home or other inpatient wards, and PSG was performed in another night within one week.

The study complied with the Declaration of Helsinki and was approved by the Institutional Review Board of Peking University People's Hospital (No. 2022PHB359-001). Written informed consent was obtained from each participant.

PSG Recordings

PSG were conducted in accordance with the recommendations of the American Academy of Sleep Medicine (AASM).[11] The following signals were recorded: electroencephalogram (F3-M2, F4-M1, C3-M2, C4-M1, O1-M2, O2-M1), bilateral electrooculogram, chin muscle electromyogram, oronasal thermistor, nasal pressure, rib cage and abdominal movement, electrocardiogram (lead 1), snoring, body position, bilateral anterior tibialis electromyograms, and pulse rate and oxygen saturation by pulse oximetry.

Portable Monitor Recordings

Philips Respironics Inc. provided the ANO devices, pads used for uploading data, analytic software, and cloud database service, with no other involvement besides. The ANO devices collected oxygen saturation and pulse rate via finger pulse oximetry, airflow via nasal cannula (nasal pressure), respiratory effort via one thoracoabdominal RIP belt, snoring and body position by central box. For ANO_{lab} monitoring, patients wore both sets of recording (PSG and ANO devices) simultaneously. As for ANO_{home}, ANO devices were worn by patients at home or in other inpatient wards, with instructions provided through an instructional card and video.

Recordings Scoring

The PSG and portable monitor recordings were scored by qualified technicians, in accordance with the AASM scoring manual. The scoring process was conducted in a blinded manner. Apneas were scored when there was a ≥90% reduction in airflow from baseline for ≥10 seconds on the oronasal thermistor signal. The same criteria used to identify obstructive, central, and mixed apneas on the portable monitor recordings were used to score those events using PSG. Hypopneas were defined by a ≥ 30% reduction in a respiratory signal for at least 10 seconds associated with a ≥ 3% reduction in

oxygen saturation or an arousal. AHI measured using PSG was calculated as the average number of apnea and hypopnea events per hour of sleep. Oxygen desaturation was defined in our laboratory as a decrease of ≥3% for both PSG and portable monitor recordings.[11] To test the discrepancy in the indices caused by the difference between total sleep time (TST) on PSG and monitoring time (MT) on ANO, we introduced a correction based on sleep efficiency. The ratio of TST to total recording time (TRT) on PSG was defined as sleep efficiency.

$$\text{corrected REI} = \text{REI} \times \frac{\text{MT (ANO)}}{\text{TRT (ANO)}} \div \frac{\text{TST (PSG)}}{\text{TRT (PSG)}}$$

Remote Data Transmission and Verification of Integrity

In addition to traditional data transmission, ANO recordings could be transmitted to a portable pad via wire, then automatically uploaded to the cloud database via a wireless network (5G cellular network in our study). The recording data could be accessed, downloaded automatically, and scored using the Sleepware G3 software, when the computers in the sleep center were connected to the Internet. Furthermore, any scoring or editing was synchronized with the cloud database. The data were downloaded and collected, then compared with the original data to verify the integrity and identity.

The Message-digest 5 (MD5) algorithm is a one-way hash function developed by Ron Rivest, which is widely used to verify file identity and integrity. It is designed to determine whether data transmitted over the internet has been altered.[12] This algorithm encrypts digital data into a 32-digit code, such as 04e12fb6213e7be8f5afd85573e24aa2. Even a minor change, such as altering one character in a file, would result in a completely different MD5 code. The ANO original data recordings were stored in .edf format. A single night's recording might generate multiple .edf files, depending on the monitoring duration. Each .edf file was assigned a unique MD5 code. Then there would be two sets of MD5 codes: one for the cloud data and one for the original data. By comparing the MD5 codes of the cloud data with those of the original data, we could verify the integrity of the cloud data and confirm its identity.

Statistical Analysis

Continuous variables were expressed as mean ± standard deviation (SD), with normality of distribution verified using the Kolmogorov–Smirnov tests. Paired t-tests were performed to assess the level of agreement between variables, while Pearson's correlation coefficient (*R*) was used to evaluate their correlation. As the primary outcome variables were the REI and AHI derived from ANO and PSG, in order to test their agreement, a statistic method described by Bland and Altman was introduced.[13,14]

For diagnostic tests, using AHI on PSG we determined the presence and severity of every patient, and test the sensitivity, specificity, likelihood ratios and positive/negative predictive values when using REI on ANO for diagnosis. We graphed identity scatter plots and sheets that patients falling into different groups diagnosed by REI on ANO compared with gold standard PSG. For remote data transmission verification, the 32-digit MD5 codes generated for remotely transmitted data were directly compared with those of the original data to verify identity and integrity. The results were presented as numbers and percentages. Data were analyzed using IBM SPSS Statistics (version 26), MedCalc (version 19) and R (version 4.4.3).

Results

Sample Overview and Success Rate

As illustrated in Figure 1, 99 and 180 patients were enrolled in the study of ANO_{lab} and ANO_{home} respectively. Of the 99 paired PSG and ANO_{lab} recordings conducted, 8 ANO_{lab} recordings failed and were excluded (6 records had short total recording time [<240 minutes], and 2 recordings had airflow signal loss [losing >50% of total recording time]). Consequently, the success rate for ANO_{lab} monitoring was 91.9% (91/99). Similarly, among the 180 ANO_{home} monitoring conducted, 10 failed and were excluded from analysis (8 records had short total recording time, and 2 records had airflow signal loss). Thus, the success rate for ANO_{home} monitoring was 94.4% (170/180).

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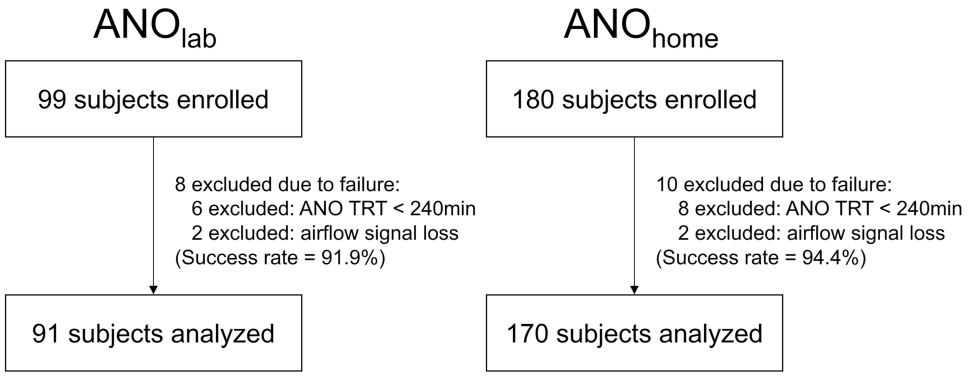

Figure 1 Diagram of the overall study flow.

The participants in the ANO_{lab} group were 78.0% male, with age of 50.1 ± 14.6 years, a body mass index (BMI) of 27.1 ± 4.1 kg/m², and an AHI of 31.6 ± 25.0 events/hour. In the ANO_{home} group, 67.3% of the participants were male, with an age of 57.0 ± 14.4 years, a BMI of 27.1 ± 3.8 kg/m², and an AHI of 35.3 ± 21.3 events/hour.

Comparison of Parameters in Sleep Reports

The results of PSG and ANO_{lab} recording were compared firstly (see Table 1). Total recording time did not show a significant difference (P = 0.054), but MT of ANO_{lab} was on average 100.6 minutes longer than TST of PSG. There was no difference between the ANO_{lab} and PSG in the number of total respiratory events and hypopnea events per night. But there were differences in the numbers of obstructive/mixed apnea events and central apnea events. Thus, the REI on ANO_{lab} was significantly lower than AHI on PSG (P < 0.001). There was no difference in ODI_3 and mean SpO_2 between ANO_{lab} and PSG. Most parameters showed strong correlation ($R \geq 0.6$) except for TRT, TST/MT and the number of central apneas.

The results of PSG and ANO_{home} recording were also compared (shown in Table 2), with similar trends to the comparison between PSG and ANO_{lab}: longer MT and lower REI on ANO_{home}. There was no significant difference between the total respiratory events on PSG and ANO_{home} (P = 0.172). Most parameters showed strong correlation ($R \geq 0.6$) except for TRT, TST/MT, the numbers of central apneas and hypopneas.

Table 1 Description and Comparison on Sleep Parameters Acquired by PSG and ANO_{lab} Recordings

	PSG (n=91)	ANO_{lab} (n=91)	Difference	P[a]	*R*	P[b]
	Mean ± SD	Mean ± SD				
TRT (min)	488.9 ± 35.9	505.4 ± 76.2	−16.5	0.054	0.113	0.286
TST / MT (min)	389.6 ± 61.9	490.2 ± 74.5	−100.6	<0.001	0.030	0.775
AHI / REI (/hr)	31.6 ± 25.0	24.9 ± 20.5	6.7	<0.001	**0.953**	**<0.001**
Respiratory events (#)	208.3 ± 171.3	203.5 ± 171.3	4.8	0.438	**0.941**	**<0.001**
- Obstructive and mixed apneas (#)	139.7 ± 156.4	122.4 ± 133.2	17.2	0.008	**0.926**	**<0.001**
- Central apneas (#)	9.2 ± 13.5	27.9 ± 38.7	−18.7	<0.001	0.498	<0.001
- Hypopneas (#)	59.3 ± 61.9	53.4 ± 55.2	5.9	0.216	**0.706**	**<0.001**
ODI_3 (/hr)	25.3 ± 24.4	26.2 ± 21.2	−0.9	0.501	**0.844**	**<0.001**
SIT90 (min)	27.6 ± 48.4	45.8 ± 81.8	−18.2	0.007	**0.649**	**<0.001**
Mean SpO_2 (%)	93.7 ± 3.2	93.6 ± 2.2	0.1	0.705	**0.733**	**<0.001**

Notes: [a]P values represented the significance of difference between parameters on PSG and ANO_{lab} by paired *t*-test. [b]P values represented the significance of correlation by paired *t*-test. Bold values denote variables demonstrating significant correlations ($R \geq 0.6$; P < 0.05).

Abbreviations: R, Pearson correlation coefficient; TRT, total recording time; MT, monitoring time (for ANO); TST, total sleep time (for PSG); REI, respiratory event index (for ANO); AHI, apnea hypopnea index (for PSG); #, number of events; ODI_3, oxygen desaturation index (decreased by ≥3%); SIT90, saturation-impaired time of oxygen saturation < 90%; SpO_2, peripheral oxygen saturation.

Table 2 Description and Comparison on Sleep Parameters Acquired by PSG and ANO_{home} Recordings

	PSG (n=170)	ANO_{home} (n=170)	Difference	P[a]	*R*	P[b]
	Mean ± SD	Mean ± SD				
TRT (min)	485.4 ± 47.1	504.5 ± 93.3	−19.0	0.015	0.063	0.409
TST / MT (min)	382.9 ± 62.0	473.4 ± 91.7	−90.4	<0.001	0.020	0.794
AHI / REI (/hr)	35.3 ± 21.3	27.2 ± 16.8	8.1	<0.001	**0.795**	**<0.001**
Respiratory events (#)	226.4 ± 145.4	215.3 ± 135.9	11.1	0.172	**0.719**	**<0.001**
- Obstructive and mixed apneas (#)	131.6 ± 137.6	95.4 ± 90.7	36.2	<0.001	**0.780**	**<0.001**
- Central apneas (#)	11.9 ± 27.7	22.2 ± 39.2	−10.3	0.001	0.382	<0.001
- Hypopneas (#)	82.3 ± 66.8	97.8 ± 83.8	−15.5	0.006	0.555	<0.001
ODI_3 (/hr)	28.5 ± 21.0	26.5 ± 17.2	2.1	0.061	**0.779**	**<0.001**
SIT90 (min)	29.7 ± 46.3	43.0 ± 64.7	−13,3	<0.001	**0.653**	**<0.001**
Mean SpO_2 (%)	93.5 ± 2.9	93.3 ± 1.9	0.1	0.384	**0.699**	**<0.001**

Notes: [a]P values represented the significance of difference between parameters on PSG and ANO_{lab} by paired *t*-test. [b]P values represented the significance of correlation by paired *t*-test. Bold values denote variables demonstrating significant correlations ($R \geq 0.6$; $P < 0.05$).
Abbreviations: R, Pearson correlation coefficient. TRT, total recording time; MT, monitoring time (for ANO); TST, total sleep time (for PSG); REI, respiratory event index (for ANO); AHI, apnea hypopnea index (for PSG); #, number of events; ODI_3, oxygen desaturation index (decreased by ≥3%); SIT90, saturation-impaired time of oxygen saturation < 90%; SpO_2, percutaneous arterial oxygen saturation.

Correlation and Agreement Between Monitoring Methods

The correlation coefficient between REI on ANO_{lab} and AHI on PSG was 0.953 (see Figure 2). Bland-Altman analysis indicated a mean difference of −6.7 events/h (95% CI: −8.4 to −4.9, P<0.001), with limits of agreement ranging from −23.0 to 9.6 events/h. When corrected REI on ANO_{lab} was compared with AHI on PSG, Bland-Altman analysis showed a mean difference of −1.1 events/h (95% CI: −2.5 to 0.3, P = 0.113).

The correlation coefficient of REI on ANO_{home} and AHI on PSG was 0.795 (see Figure 3). The Bland-Altman plot revealed a mean difference of −8.0 events/h (95% CI: −9.9 to −6.0, P < 0.001), with limits of agreement ranging from –30.7 to 17.3 events/h. When corrected REI on ANO_{home} was compared with AHI on PSG, Bland-Altman analysis showed a mean difference of −1.9 events/h (95% CI: −4.1 to 0.3, P = 0.093).

Diagnostic Accuracy

Table 3 compares the diagnostic performance of ANO_{lab} and ANO_{home} across different REI thresholds. With a threshold of REI ≥ 5 events/h, ANO_{lab} had 97.4% sensitivity, 92.9% specificity, 98.7% positive predictive value, 86.7% negative predictive value and 96.7% accuracy. For patients with moderate-to-severe OSA whose AHI was ≥15 events/h, ANO_{lab} exhibited reduced sensitivity (86.4%) but improved specificity (96.9%). For ANO_{home}, a threshold of REI ≥ 5 events/h

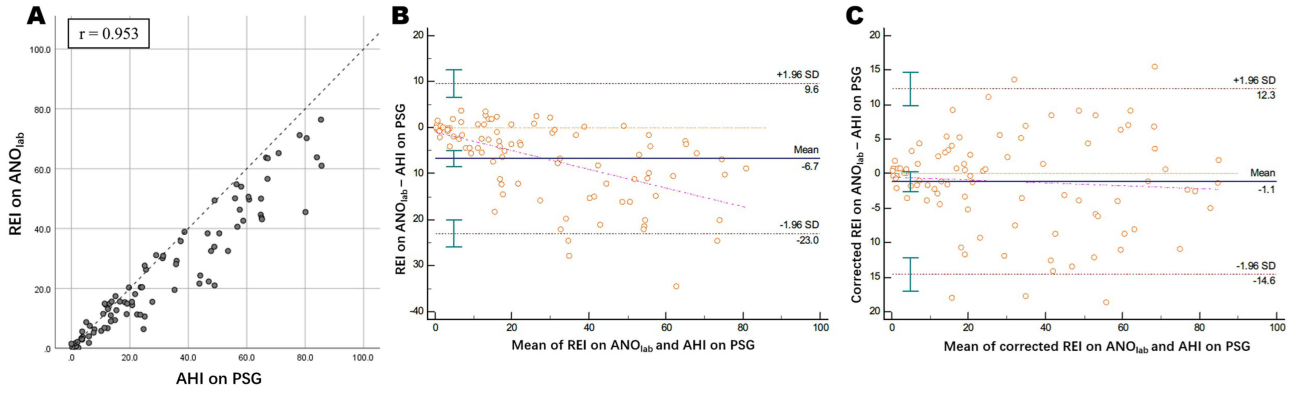

Figure 2 Scatter plot and Bland-Altman plot of REI on ANO_{lab} and AHI on PSG, and Bland-Altman plot of corrected REI on ANO_{lab} and AHI on PSG. (n = 91). (**A**) Scatter plot of REI on ANO_{lab} and AHI on PSG. (**B**) Bland-Altman plot of REI on ANO_{lab} and AHI on PSG. (**C**) Bland-Altman plot of corrected REI on ANO_{lab} and AHI on PSG. * For detailed statistical results of Bland-Altman analyses, such as regression equation, see Supplementary Table S1.

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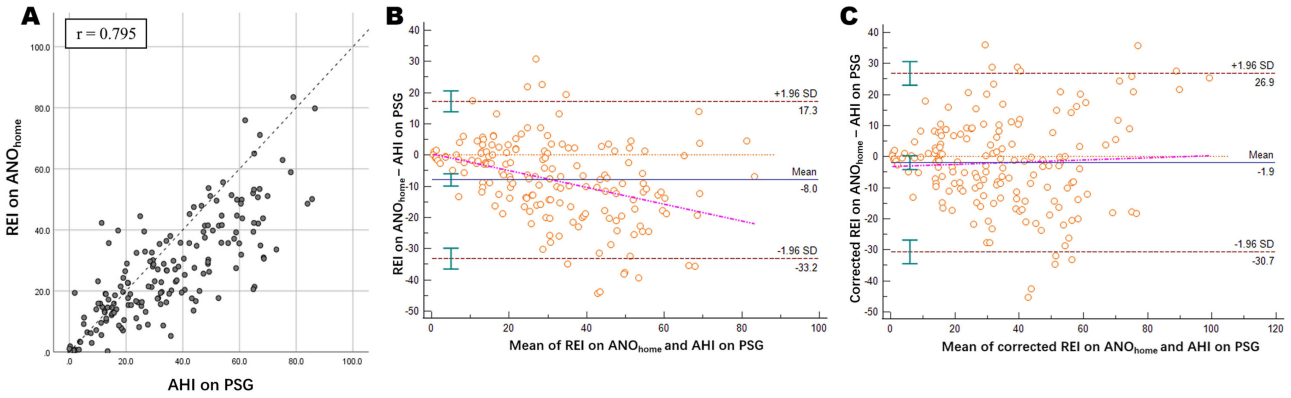

Figure 3 Scatter plot and Bland-Altman plot of REI on ANO_{home} and AHI on PSG, and Bland-Altman plot of corrected REI on ANO_{home} and AHI on PSG. (n = 170). (**A**) Scatter plot of REI on ANO_{home} and AHI on PSG. (**B**) Bland-Altman plot of REI on ANO_{home} and AHI on PSG. (**C**) Bland-Altman plot of corrected REI on ANO_{home} and AHI on PSG. * For detailed statistical results of Bland-Altman analyses, such as regression equation, see Supplementary Table S1.

resulted in 98.8% sensitivity, 90.0% specificity, 99.4% positive predictive value, 81.8% negative predictive value and 98.2% accuracy. For patients with moderate-to-severe OSA whose AHI was ≥15 events/h, ANO_{home} had decreased sensitivity (88.9%) but maintained relatively high specificity (74.3%).

Figure 4 presents the receiver operating characteristic (ROC) curves comparing the diagnostic performance of REI and corrected REI from ANO_{lab} and ANO_{home} for detecting OSA and moderate-severe OSA. ANO_{lab} demonstrated excellent diagnostic accuracy, with REI showing AUC values of 0.991 (OSA) and 0.959 (moderate-severe OSA), corresponding to optimal cutoff values of 5.7 (sensitivity 95%, specificity 100%) and 15.15 (sensitivity 84%, specificity of 97%), respectively. Similarly, ANO_{home} showed strong performance with AUCs of 0.955 (OSA) and 0.868 (moderate-severe OSA), with best cutoff thresholds at 4.05 (sensitivity 98%, specificity 90%) and 19.45 (sensitivity 71%, specificity 91%), respectively. While the Youden index-optimized cutoffs favored specificities, clinical consideration of ANO_{home}'s REI underestimation suggested adopting REI ≥15.9 (sensitivity 81%, specificity 80%) as a balanced threshold for moderate-severe OSA detection. Corrected REI values exhibited largely comparable diagnostic accuracy across both systems.

ANO vs PSG Based on OSA Severity

Figure 5 illustrates the numbers and percentage of subjects categorized as having no OSA, mild, moderate, or severe OSA based on AHI on PSG or REI on ANO_{lab}/ANO_{home}. Consistent with the agreement between PSG and ANO_{lab}, the proportions in each clinical grouping were similar for these two methods. Compared to PSG, ANO_{home} identified a higher proportion of participants in the moderate OSA group and a lower proportion in the severe OSA group. Although ANO_{lab}

Table 3 Diagnostic Test of ANO_{lab} and ANO_{home} Compared with Different Cutoffs of REI Compared with Gold Standard PSG

	REI cutoffs	Prevalence	Sensitivity (95% CI)	Specificity (95% CI)	LR+	LR-	PPV	NPV	Accuracy
ANO_{lab} (n=91)	≥5	0.846	0.974 (0.909, 0.997)	0.929 (0.661, 0.998)	13.6	0.028	0.987	0.867	0.967
	≥15	0.648	0.864 (0.750, 0.940)	0.969 (0.838, 0.999)	27.6	0.140	0.981	0.795	0.901
	≥30	0.481	0.821 (0.644, 0.909)	0.976 (0.899, 1.000)	34.5	0.184	0.970	0.854	0.901
ANO_{home} (n=170)	≥5	0.941	0.988 (0.932, 0.990)	0.900 (0.555, 0.997)	9.88	0.014	0.994	0.818	0.982
	≥15	0.759	0.889 (0.823, 0.936)	0.743 (0.567, 0.875)	3.46	0.150	0.930	0.634	0.859
	≥30	0.613	0.613 (0.488, 0.690)	0.883 (0.790, 0.945)	5.24	0.438	0.864	0.654	0.735

Abbreviations: REI, respiratory event index; CI, confidence interval; LR+, positive likelihood ratio; LR-, negative likelihood ratio; PPV, positive predictive value; NPV, negative predictive value.

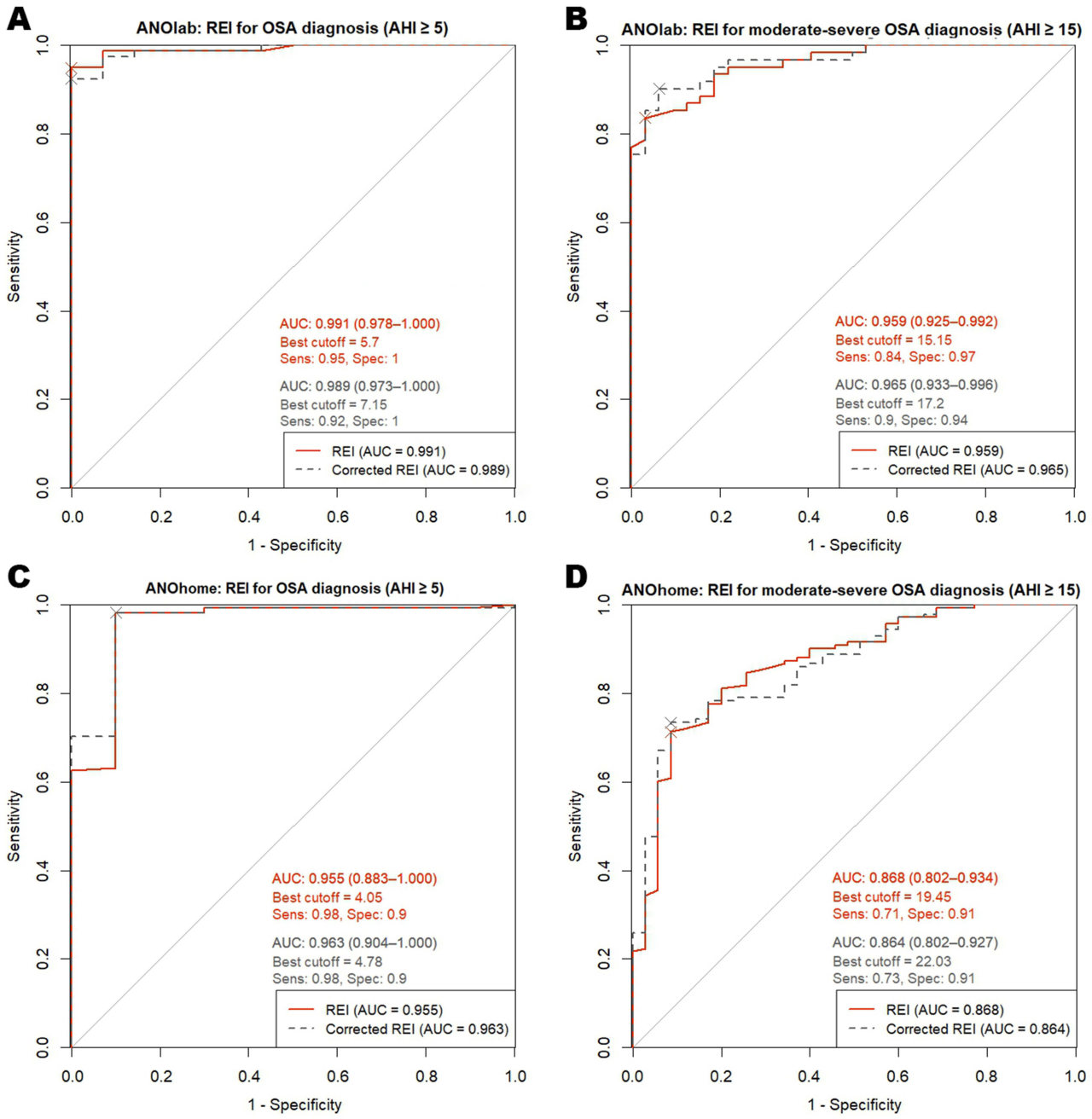

Figure 4 Receiver operating characteristic (ROC) curve evaluating REI diagnostic accuracy for OSA. (**A**) ANO_{lab}: REI performance in diagnosing OSA (AHI ≥ 5). (**B**) ANO_{lab}: REI performance in diagnosing moderate-severe OSA (AHI ≥ 15). (**C**) ANO_{home}: REI performance in diagnosing OSA (AHI ≥ 5). (**D**) ANO_{home}: REI performance in diagnosing moderate-severe OSA (AHI ≥ 15).

and ANO_{home} demonstrated occasional misclassification across OSA severity categories, no instances of gross misclassification (eg, labeling moderate-severe OSA as non-OSA) were observed.

Reliability in Remote Data Transmission

A total of 129 recordings (63 ANO_{lab}, 66 ANO_{home}) were uploaded, with 126 (62 ANO_{lab}, 64 ANO_{home}) successful uploads, resulting in a success rate of 97.7%. Utilizing MD5 algorithm, the tool for verifying file integrity and identity, we generated 126 pairs of MD5 code sets for 126 original recordings that were transmitted via wire, and for 126 corresponding cloud data recordings. A total of 1205 pairs of MD5 codes were generated, for 1205 .edf files. The

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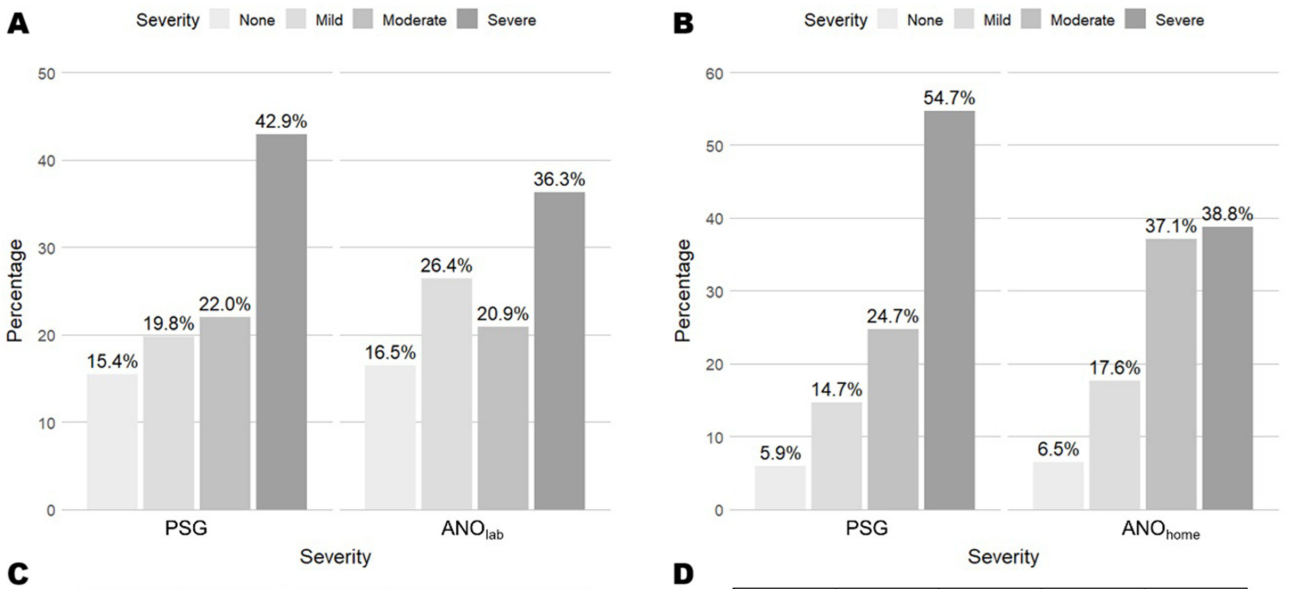

C

PSG / ANOlab	None	Mild	Moderate	Severe
None	13	2	0	0
Mild	1	15	8	0
Moderate	0	1	11	7
Severe	0	0	1	32

D

PSG / ANOhome	None	Mild	Moderate	Severe
None	9	2	0	0
Mild	0	15	13	2
Moderate	1	6	22	34
Severe	0	2	7	57

Figure 5 The percentages and numbers of patients falling into clinical OSA groupings based on PSG and ANO_{lab} (left) or ANO_{home} (right) results. (**A**) Proportional distribution of patients across clinical OSA severity groups, comparing AHI on PSG and REI on ANO_{lab}. (**B**) Proportional distribution of patients across clinical OSA severity groups, comparing AHI on PSG and REI on ANO_{home}. (**C**) The numbers of patients falling into clinical OSA groupings based on AHI on PSG and REI on ANO_{lab}. (**D**) The numbers of patients falling into clinical OSA groupings based on AHI on PSG and REI on ANO_{home}. None: AHI or REI < 5; Mild: AHI or REI ≥5 and <15; Moderate: AHI or REI ≥15 and <30; Severe: AHI or REI ≥30.

analysis revealed that 1199 pairs (99.50%) of MD5 codes from the two transmission methods were identical, confirming that the uploading and downloading processes did not compromise recording integrity or alter the data.

Furthermore, our practice demonstrated that scoring could be reliably performed using cloud data, with any modifications – such as scoring adjustments or report generation – seamlessly synchronized, provided the scoring device was connected to the Internet.

Discussion

The results demonstrated a relatively good performance in screening and diagnosing OSA by ANO monitoring, as evidenced by the strong correlation between PSG and ANO recordings, both in-lab and out of sleep center. A comparison of total respiratory events recorded by PSG and simultaneous ANO_{lab} monitoring revealed no significant differences, indicating the reliability of ANO signals. Both ANO_{home} and ANO_{lab} demonstrated high sensitivity and specificity in OSA diagnosis, as well as in identifying moderate-to-severe OSA. Additionally, this study showed that the data collected by ANO could be successfully transmitted wirelessly, with the MD5 algorithm ensuring the integrity and identity of the transmitted data.

Currently, thoracoabdominal movements monitoring remains most frequently used for detecting respiratory effort during sleep, using RIP, piezoelectric or polyvinylidene difluoride (PVDF) belts.[4] AASM does not recommend the use of 1 RIP belt, 2 or 1 piezo belt and other effort measures due to the scanty publication of regarding researches,[9] and AASM scoring manual (version 3) listed "single thoracoabdominal RIP belt" as acceptable.[11] European Respiratory Society (ERS) does not require a specific number of RIP belts in its technical standards for type 3 PM, and describes RIP as often is a "back-up" signal for detecting respiratory events.[4] Prior to our study, several studies tested the performance of different PMs using single-belt respiratory effort recording, as listed in Table 4. Our study extended this research by validating the reliability of ANO, a type 3 PM with single RIP belt, in detecting respiratory events and identifying OSA patients. Notably, ANO demonstrated superior performance with higher sensitivities and specificities compared to other PMs, while maintaining its distinctive advantage in data teletransmission capabilities. All of these studies showed that a single belt could reliably monitor respiratory effort signals in patients with OSA. Thinking about all the above, the single-belt technology could be recommended for the diagnosing of OSA in patients with a high pretest probability of moderate-to-severe OSA besides the current guideline recommendation.

Noticed by our study, single-belt technology may occasionally face challenges in distinguishing central from obstructive or mixed respiratory events. As during the obstructive events, the respiratory movement of chest and abdomen could be contradictory, and the single-belt might mistake these events as central ones. However, since central apneas typically constitute only a minor proportion of total respiratory events in OSA patients, this limitation does not significantly impact the overall diagnostic accuracy for OSA. We also suggested that particular attention must be paid to ensuring proper RIP belt tightness during testing, as this critically affects respiratory effort signal quality. Notably, ANO may demonstrate a slight tendency to overestimate central apneas. Therefore, following strategies should be recommended. Comprehensive sleep evaluation must be supervised by a sleep medicine practitioner before using PM. When HSAT results show a substantial number of central apneas or pattern of Cheyne-Stokes breathing, PSG should be performed. Patients with known predisposing factors for central sleep apnea (such as heart failure) should be considered for PSG or other validated portable devices, but not this kind of single-belt technology.

In the simultaneous monitoring of ANO_{lab} and PSG, MT on ANO_{lab} was on average 100.6 minutes longer than TST on PSG, as the lack of sleep staging in ANO tended to result in lower indices on ANO. The significant differences between REI and AHI were observed mainly because of the variation between MT and TST.[19–22] In both Bland-Altman analyses of REI on ANO and AHI on PSG, regression analysis indicated a negative correlation between the difference and mean (Figures 2B, 3B and supplementary Table S1), suggesting that in patients with higher AHI values, ANO_{lab} and ANO_{home} were more likely to underestimate of the REI, resulting in a larger difference between REI on ANO_{lab}/ANO_{home} from the actual AHI. After the correction of REI on ANO_{lab} and ANO_{home} using sleep efficiency, both Bland-Altman analyses showed no significant difference between those two REI and AHI. The discrepancy between recording time and sleep time has been an important factor influencing the indices in portable monitoring devices, and similar results were reported in other studies of type 3 PMs in OSA. Cho et al found that sleep efficiency negatively correlated

Table 4 Characteristics of Studies Comparing Single-Belt Type 3 PMs and PSG

Study, Country	Device (SCOPER Classification)	Type of Belt	N	AHI Threshold	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Cho 2017, South Korea[15]	ApneaLink Plus ($S_0C_4O_{1x}P_2E_4R_2$)	Pneumatic sensor belt	149	AHI ≥ 5 AHI ≥ 15	93.0 75.0	61.9 86.9	93.7[a] 89.2[a]	59.2[a] 70.7[a]
Cheliout-Heraut 2011, France[16]	Somnolter ($S_4C_4O_{1x}P_2E_2R_2$)	Plethysmography inductance belt	90	AHI ≥ 5	83.6	81.8	98.2[a]	29.6[a]
Santos-Silva 2009, Brazil[17]	Stardust II ($S_0C_4O_{1x}P_2E_4R_2$)	Piezoelectric sensor belt	80	AHI ≥ 5 AHI ≥ 15	93 85	59 80	85 80	76 84
Polese 2013, Brazil[18]	Stardust II ($S_0C_4O_{1x}P_2E_4R_2$)	Piezoelectric sensor belt	43	AHI ≥ 5 AHI ≥ 15	90 80	30 60	90 88	60 45
Our study	Alice NightOne ($S_0C_4O_{1x}P_2E_2R_2$)	Plethysmography inductance belt	91 + 170	AHI ≥ 5	97.4 (lab) 98.8 (home)	92.9 (lab) 90.0 (home)	98.7 (lab) 99.4 (home)	86.7 (lab) 81.8 (home)
				AHI ≥ 15	86.4 (lab) 88.9 (home)	96.9 (lab) 74.3 (home)	98.1 (lab) 93.0 (home)	79.5 (lab) 63.4 (home)

Notes: [a]Not reported in the original study, but calculated by the sensitivity, specificity and prevalence.
Abbreviations: PM, portable monitor; AHI, apnea hypopnea index; PPV, positive predictive value; NPV, negative predictive value.

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with the AHI difference, while the arousal index positively correlated in their validation study of the ApneaLink Plus.[15] Xu et al addressed this issue by collecting self-reported sleep duration and modifying the monitoring time by the responses and recorded activity signals to generate more precise indices.[23] In further practice, greater efforts should be made to estimate total sleep time more accurately to enhance the reliability of portable monitoring devices.

Both ANO_{home} and ANO_{lab} demonstrated reliable value in OSA diagnosis. However, Bland-Altman analysis between REI on ANO_{home} with AHI on PSG showed a mean difference of −8.0 events/h, which was thought to be contributed by the known night-to-night variability of sleep and the discrepancy between MT and TST.[24–26] The maximum one-week interval between PSG and ANO_{home} testing was designed to minimize night-to-night variability, while acknowledging that complete elimination of this inherent physiological fluctuation was unachievable. Moreover, as ANO lacked a method such as electroencephalogram to detect arousal events, it identified fewer hypopneas, resulting in a reduced REI. As illustrated in Figure 5, while ANO_{home} results were effective in diagnosing OSA, they tended to underestimate the severity of OSA, primarily due to the same factors as in prior papers.[27,28]

While the underestimation of REI on ANO_{lab}/ANO_{home} may largely contribute to the discrepancy in TST and MT, and corrected by sleep efficiency, the persistent gap could have implications in clinical practice, such as missed or delayed diagnosis in mild-to-moderate OSA patients. However, our study demonstrated that ANO_{home} maintained high sensitivity (98.8% for OSA and 88.9% for moderate-to-severe OSA), supporting its utility as a screening or diagnostic tool. To mitigate underestimation, potential clinical strategies should be considered: For high-risk phenotypes (eg, high BMI, or comorbid with hypertension), a more proactive treatment approach may be warranted, even with borderline REI values; For symptomatic patients, such as showing high ESS scores, with REI values between 5 and 15, confirmatory PSG should be performed if available or choose a lower cutoff of REI for treatment; For patients with insomnia complaints, ANO_{home} may not be the optimal diagnostic tool, and alternative PSG should be prioritized.

Telemedicine, consisting of all stages of diagnosis, treatment and follow-up, has gained wide acceptance across various medical specialties.[10] For sleep-related breathing disorders, the data teletransmission of PSG or home monitoring plays a crucial role. Though the reliability of PSG data teletransmission has been validated in previous studies,[29–31] researches on the teletransmission and telediagnosis of HSAT devices remained limited. In our study, the HSAT data collected by ANO was successfully transmitted wirelessly, as supported when the integrity and identity of the transmitted data ensured by the MD5 algorithm. These results demonstrated the reliability of ANO in remote data transmission, providing a robust foundation for the telediagnosis and follow-up of OSA.[32] However, from our experience, the uploading process was somewhat complex for the general population. The ANO system utilized Philips Sleepware G3 software - the same platform employed for PSG scoring and other professional sleep monitoring devices. While this software provided comprehensive functionality for healthcare professionals, its interface complexity created barriers for other users, including the multiplicity of buttons and functions designed for specialist use, the non-intuitive sequence of operations required for data upload, and interface elements with small font sizes on tablet devices. Developing a simplified one-click, intuition-driven interface and optimizing the uploading process would likely improve feasibility in practical telemedicine applications. Furthermore, several practical implementation challenges must be considered for real-world telemedicine applications, such as the need for standardized protocols to accommodate varying levels of technical infrastructure across clinical settings, to account for potential internet connectivity issues and to establish clear contingency protocols for failed transmissions.

However, our study had several limitations. Firstly, the sequence of in-laboratory monitoring of PSG and HSAT was not fixed. As the “first-night effect” in the sleep laboratory may lead to some changes in sleep architecture, the different sequence might lead to different impact on sleep-related parameters.[33] Secondly, the data in our study were uploaded by technicians rather than patients themselves, which did not fully reflect real-world telemedicine scenarios. Thirdly, when the subjects conducted the HSAT, they should be told to record the estimated sleep time and other influence factors to reduce the bias between in center PSG and HSAT. Lastly, the further validation study should explore these findings in diverse clinical populations, particularly those with comorbid conditions, to enhance generalizability.

Conclusion

In summary, the study proves that Alice NightOne is a reliable type 3 portable monitor with single thoracoabdominal belt for diagnosis of OSA. Its good sensitivity and specificity in both in-laboratory and home monitoring, coupled with its robust remote data transmission function, positions it as a valuable tool for facilitating telediagnosis and management of OSA patients, potentially improving access to care. The system, including the monitor device and the remote data transmission kit, will provide a new access for the patients with suspected OSA.

Abbreviations

AASM, American Academy of Sleep Medicine; AHI, apnea-hypopnea index; ANO, Alice NightOne; ANO_{home}, home sleep apnea testing using Alice NightOne; ANO_{lab}, in-laboratory Alice NightOne monitoring; BMI, body mass index; CI, confidence interval; ERS, European Respiratory Society; HSAT, home sleep apnea testing; LR+, positive likelihood ratio; LR-, negative likelihood ratio; MD5, Message digest-5; MT, monitoring time; NPV, negative predictive value; ODI_3, oxygen desaturation index (decreased by ≥3%); OSA, obstructive sleep apnea; PM, portable monitor; PPV, positive predictive value; PSG, polysomnography; *R*, Pearson correlation coefficient; REI, respiratory event index; RIP, respiratory inductance plethysmography; ROC, receiver operating characteristic; SD, standard deviation; SIT90, saturation-impaired time of oxygen saturation < 90%; SpO_2, percutaneous arterial oxygen saturation; TRT, total recording time; TST, total sleep time.

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author, XiaoSong Dong, upon reasonable request.

Author Contributions

MaoHuan Peng: Data curation, software, formal analysis, visualization, and writing – original draft.

YuanYuan Zhang: Methodology, resources, validation, visualization, and writing – original draft.

Rui Zhao, LiHua Deng, XinRu Wang, XueLi Zhang, Jing Li, Long Zhao, Bing Zhou: Data curation, investigation, writing – review and editing.

XiaoSong Dong: Conceptualization, supervision, funding acquisition, writing – review and editing.

Fang Han: Conceptualization, resources, project administration, writing – review and editing.

All authors gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agreed to be accountable for all aspects of the work.

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Disclosure

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