Original Article

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Validation of a sheet-shaped body vibrometer for screening of obstructive sleep apnea

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Summary **We assessed the validity of using a sheet-shaped body vibrometer (SBV) as a portable monitoring device for obstructive sleep apnea (OSA) screening. Seventy consecutive patients with suspected OSA underwent simultaneous in-laboratory polysomnography (PSG) and SBV. We evaluated the screening accuracy of the respiratory event index (REI) obtained with the SBV, using the REI based on either the estimated total sleep time (REI_eTST) or time in bed (REI_TIB); these were compared to the apnea-hypopnea index (AHI) obtained *via* PSG. Bland-Altman plots indicated that the mean difference between REI_eTST and AHI was lower than that between REI_TIB and AHI (1.2 ± 19.8 *vs.* 6.5 ± 16.8). For AHI ≥ 15, the sensitivity and specificity at an optimal REI_eTST of 17.0 were 90.9% and 76.9%, whereas those at an optimal REI_TIB of 15.9 were 86.4% and 80.8%, respectively; moreover, for AHI ≥ 30, these values at an optimal REI_eTST of 26.0 were 89.5% and 88.2%, whereas those at an optimal REI_TIB of 23.8 were 84.2% and 92.2%, respectively. The optimal cutoff values of REIs for AHI of ≥ 5 were markedly different from those for AHI obtained *via* PSG (REI_eTST, 14.9; REI_TIB, 15.0), but close to those for AHI of ≥ 15; both had good sensitivities and specificities. REIs obtained *via* SBV performed well in moderate-to-severe, but not mild, OSA screening; REI_eTST showed a slightly higher sensitivity and a relatively closer value to the AHI obtained *via* PSG when compared to REI_TIB. We consider the SBV less acceptable for screening mild cases than more severe cases.**

Keywords: Obstructive sleep apnea, sheet-shaped body vibrometer, portable monitor, validation, estimated total sleep time

1. Introduction

Obstructive sleep apnea (OSA) is a known risk factor for cardiovascular morbidities, and is associated with mortality, cognitive dysfunction, deteriorated health-related quality of life, and sleepiness-related motor vehicular or occupational accidents (*1*). The prevalence of moderate-to-severe OSA in cases with an apnea-hypopnea index (AHI) of ≥ 15 events/h during overnight full polysomnography (PSG) was estimated as 7-14% in men and 2-7% in women in Western countries (*2-4*). In Asia, however, the prevalence of the disorder is estimated as 10.1% in men and 4.7% in women in the Korean population aged 40-69 years (*5*), and 5.3% in men (*6*) and 1.2% in women (*7*) in the Chinese population aged 30-60 years.

Attended in-laboratory PSG with subsequent manual scoring of the data is the gold standard for OSA diagnosis. However, PSG cannot be performed in all patients suspected to have OSA, as this examination requires a specialized laboratory for recording and is both labor and time consuming. Hence, it is believed 82% of men and 93% of women with moderate-to-severe OSA remain undiagnosed (*8*). Therefore, there

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is a need for a convenient and ambulatory portable monitor (PM) with a high screening accuracy for OSA that facilitates a reduced time to diagnosis (*9,10*).

Data loss due to detached sensors during PM recording (*11*), and discomfort from sensor attachment (*12*), have been recognized as important issues of PM. The longer duration required for attaching the PM sensors may also increase patient discomfort (*11*). These issues can be resolved by PM recording without the need for attaching sensors, *i.e.*, non-wear PM devices. Previous studies on the validity of OSA screening with non-wear PM devices, such as a static charge sensitive bed (SCSB) (*13,14*) and a sheet-shaped device placed on a mattress (*15-17*), have been conducted. However, due to the insufficient number of validation studies, these devices have been classified as type 4 PM for the screening of OSA, and have hence not been generally accepted (*9,11*).

In fact, both type 3 and type 4 PM devices do not record variables required for sleep stage scoring (*i.e.*, electro-encephalography, electro-oculography, and electro-myography). Hence, the respiratory event index (REI) recorded with these types of PM has not been calculated as respiratory events per hour of total sleep time (TST), but as the events per hour of time in bed (TIB), which is longer than the TST (*18*). Therefore, the REI value is likely to be lower than the AHI, even though the respiratory events may be accurately measured with these devices. This limitation can be partially overcome through the combined use of wrist actigraphic recording, which allows TST estimation (*18*). However, the combined use of these devices increases the difficulty and complexity of the procedure.

NEMURI SCAN (NN-1100; PARAMOUNT BED CO., LTD., Tokyo, Japan) is a sheet-shaped body vibrometer (SBV), equipped with a highly sensitive pressure sensor, which detects body vibration through a mattress. This system has been shown to score sleep/wake states and calculate the estimated total sleep time (eTST) with almost the same accuracy as wrist actigraphy (*19*). Moreover, a SBV set under a mattress can detect small respiration- or heartbeat-related movements. Thus, by analyzing respiratory movements, the SBV can identify and score respiratory disturbances (*i.e.*, apneas or hypopneas), and accordingly calculate both eTST and respiratory events simultaneously. In our preliminary study on 20 patients with OSA, REI based on eTST (REI_eTST) was more similar to the AHI obtained *via* PSG in moderate ($15 \leq AHI < 30$) to severe ($AHI \geq 30$) OSA patients relative to REI based on TIB (REI_TIB) (*20*). However, we could not evaluate the screening accuracy of all OSA cases, including the mild OSA cases ($AHI \geq 5$) in that study, because most of the subjects had $AHI \geq 15$. Hence, in the present study, we aimed to assess the validity of SBV for OSA screening in a larger sample of not only moderate-to-severe OSA cases, but also mild cases and normal subjects.

2. Materials and Methods

2.1. *Subjects*

The study protocol was approved by the institutional review boards of both the Neuropsychiatric Research Institute and Tokyo Dental College Ichikawa General Hospital. We enrolled 70 consecutive patients (men, 58; women, 12; mean age, 48.5 ± 13.1 years; mean BMI, 26.1 ± 5.2 kg/m^2) who visited the outpatient clinic of the Yoyogi Sleep Disorder Center from January 2013 to November 2013 or Tokyo Dental College Ichikawa General Hospital from June 2011 to July 2011, with suspected OSA, based on findings of excessive daytime sleepiness, habitual snoring, or apnea events reported by their family members. They provided written informed consent for study participation, and consented to the simultaneous recordings of in-laboratory PSG and SBV. Among these patients, 20 from Tokyo Dental College Ichikawa General Hospital were already examined in our preliminary study (*20*).

2.2. *Polysomnography*

Diagnostic nocturnal PSG was performed using Alice 5 (Philips Respironics, Murrysville, PA, USA) or Embla N7000 (Natus Medical Inc., San Carlos, USA). The PSG montage included electroencephalogram (EEG; C3-A2, C4-A1, O1-A2, O2-A1), bilateral electro-oculogram, submental electromyogram, electrocardiogram, respiratory airflow (nasal pressure and thermistor), respiratory movements of the thorax and abdomen (inductance plethysmography), percutaneous oxyhemoglobin saturation (SpO2), snoring sound, and body position. The sleep stages were scored every 30 seconds according to the criteria of Rechtschaffen and Kales (*21*), whereas arousals were scored according to the American Sleep Disorders Association (ASDA) arousal criteria (*22*). The episodes of apnea/hypopnea were determined based on the American Academy of Sleep Medicine (AASM) criteria (*23*); accordingly, apnea was defined as the complete cessation of airflow for ≥ 10 s, whereas hypopnea was defined as a ≥ 50% reduction in airflow amplitude for ≥ 10 s or a discernible reduction for ≥ 10 s related to either arousal or oxygen desaturation of at least 3%.

2.3. *Sheet-shaped body vibrometer*

The SBV is equipped with a highly sensitive pressure sensor that detects body vibration generated by an examinee lying on a mattress. The pressure detected by the SBV changes in synchrony with expiration and inspiration; thus, the SBV measures respiratory-induced pressure changes, which are automatically adjusted for, to generate a respiratory waveform. The measured SBV value reaches the ceiling of the measurement range when

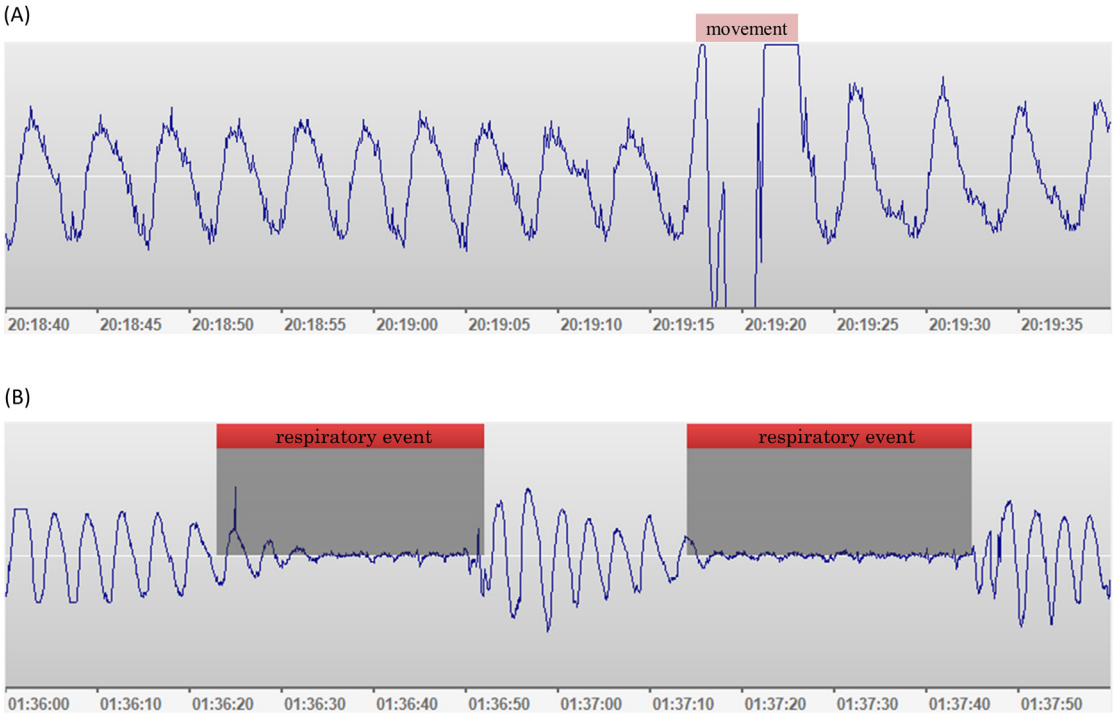

Figure 1. Respiratory waveform measured with the sheet-shaped body vibrometer. (A) movement of the examinee; **(B)** serial appearance of apnea-hypopnea events.

the examinee moves (Figure 1a). Thus, the respiratory waveform amplitudes represent the level of respiratory effort, and change (increase/decrease) based on the occurrence of apnea or hypopnea events (Figure 1b).

In the present study, the SBV was placed under a mattress, approximately 40 cm apart from its upper edge (Yoyogi Sleep Disorder Center: width, 120 cm; thickness, 15.5 cm; length, 195 cm; Tokyo Dental College Ichikawa General Hospital: width, 91 cm; thickness, 8.5 cm; length, 191 cm). The length, width, and thickness of the SBV itself was approximately 28.6 cm, 77 cm, and 1.1 cm, respectively. Using the SBV, the patients' body vibrations, including respiratory movements, were recorded simultaneously along with the PSG recordings.

The respiratory events obtained with the SBV were automatically scored, based on the findings of our preliminary study (*20*). Accordingly, respiratory events (apnea or hypopnea) were defined as follows: 1) a ≥ 30% reduction in the amplitude of the respiratory waveform from the mean amplitude of the previous 2 breaths, which lasted for at least 10 s, followed by body movement or amplitude recovery to a level greater than the mean amplitude; or 2) a consecutive increase in the amplitude of respiratory effort, more than 5 times. We also calculated the eTST based on the SBV sleep/wake data, scored according to our already published algorithm (*19*). The 2 REIs obtained *via* SBV included the respiratory events per hour of eTST (REI_eTST) and the value per hour of the total time from light-off to light-on (REI_TIB).

2.4. *Statistical analysis*

For comparisons between eTST obtained *via* SBV and TST obtained *via* PSG, between REI_TIB (/h) and AHI (/h) obtained *via* PSG, and between REI_eTST (/h) and AHI, the Wilcoxon signed rank test was performed. Pearson's correlation coefficient was used to analyze the correlations between eTST and TST, between REI_eTST and AHI, and between REI_TIB and AHI. Bland-Altman plots (*24*) were used to assess the agreement between the REIs and AHI. In the present study, we conducted receiver operating characteristic (ROC) curve analysis to determine the optimal cutoff value for predicting AHI of 5 events/h, 15 events/h, and 30 events/h by calculating the area under the ROC curves (AUC). Therefore, we calculated the sensitivities, specificities, positive and negative predictive values, positive and negative likelihood ratios, and the kappa coefficient at the respective optimal REI values for AHI of 5 events/h, 15 events/h, and 30 events/h. Statistical analyses were performed using EZR (*25*) (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria). p values < 0.05 were considered statistically significant.

3. Results

All the patients successfully underwent simultaneous recordings with PSG and SBV without any data loss. The demographic variables and sleep variables for both

PSG and SBV recordings are presented in Table 1.

The Wilcoxon signed rank test indicated that the eTST (401 ± 75.0 min) was significantly longer than the TST (380 ± 66.2 min; $p < 0.001$). Moreover, the eTST was significantly correlated with the TST ($r = 0.431$, $p < 0.001$).

The Wilcoxon signed rank test also showed that the REI_TIB (19.5 ± 9.1) was significantly lower than the AHI (26.1 ± 22.7; $p = 0.040$). However, the REI_eTST did not significantly differ from the AHI ($p = 0.84$). Fair correlations between the REI_TIB and AHI ($r = 0.764$, $p < 0.001$; Figure 2a) and between the REI_eTST and AHI ($r = 0.625$, $p < 0.001$; Figure 2b) were noted.

Bland-Altman plots revealed that both the REI_TIB and REI_eTST tended to overestimate the REI, relative to the AHI, in cases with low AHI, and also tended to underestimate the REI as the AHI value increased (Figure 3). The mean difference between the REI_eTST and AHI was lower than that between the REI_TIB and AHI (1.2 ± 19.8 *vs*. 6.5 ± 16.8; Figure 3).

The results of ROC curve analysis are presented in Figure 4. The optimal cutoff values for predicting AHI ≥ 5 were 14.9 for REI_eTST and 15.1 for REI_TIB, those for predicting AHI ≥ 15 were 17.0 for REI_eTST and 15.9 for REI_TIB, and those for predicting AHI ≥ 30 were 26.0 for REI_eTST and 23.8 for REI_TIB.

The sensitivity, specificity, and kappa coefficient for a REI_eTST of 14.9 as a cutoff value for predicting

Table 1. Demographic and polysomnographic parameters of the participants ($n = 70$)

Variable	Value	Range
Gender (male/female)	58:12	
Age (years)	48.5 ± 13.1	20 - 80
Body mass index (kg/m^2)	26.1 ± 5.2	18.7 - 46.3
Height (cm)	168 ± 8.8	142 - 184
Weight (kg)	74.1 ± 18.4	46.0 - 137
PLMI (episodes/h)	6.4 ± 14.2	0 - 65.5
AHI (episodes/h)	26.1 ± 22.7	0.8 - 90.8
REI_TIB (episodes/h)	19.5 ± 9.1	4.7 - 47.5
REI_eTST (episodes/h)	24.9 ± 23.0	5.0 - 184.9
Time in bed (min)	461 ± 41.7	381 - 578
Total sleep time (min). measured by PSG	380 ± 66.2	242 - 510
Total sleep time (min), estimated by SBV	401 ± 75.0	111 - 562
Sleep efficiency (%), measured by PSG	82.3 ± 11.8	49.8 - 97.7
Sleep efficiency (%), estimated by SBV	87.2 ± 13.7	21.0 - 99.5

PLMI: periodic leg movement index; AHI: apnea hypopnea index; REI: respiratory event index; REI_TIB: REI per hour of time in bed; REI_eTST: REI per hour of estimated total sleep time; PSG: polysomnography; SBV: sheet-shaped body vibrometer.

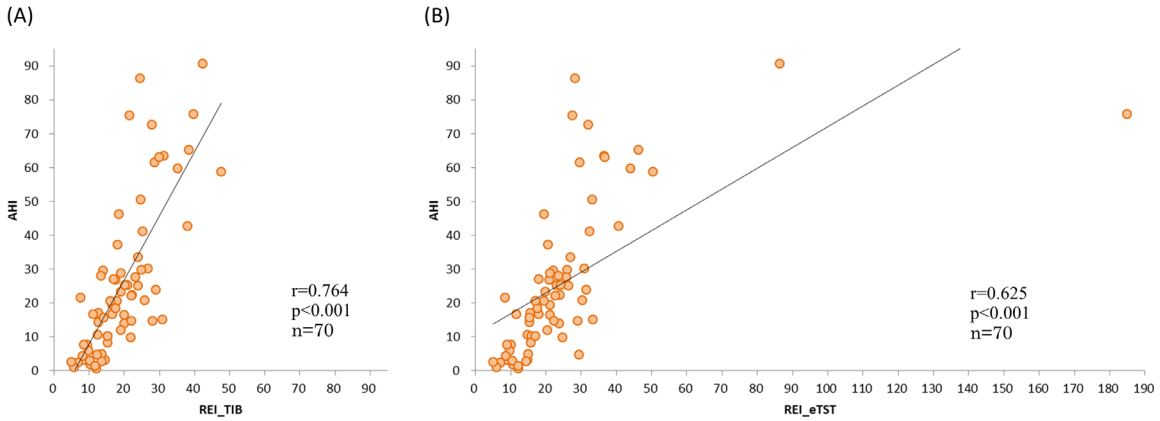

Figure 2. Pearson's correlation coefficient between the apnea-hypopnea index (AHI) and respiratory event index (REI). (A) REI per hour of time in bed (REI_TIB) and AHI; **(B)** REI per hour of estimated total sleep time (REI_eTST) and AHI.

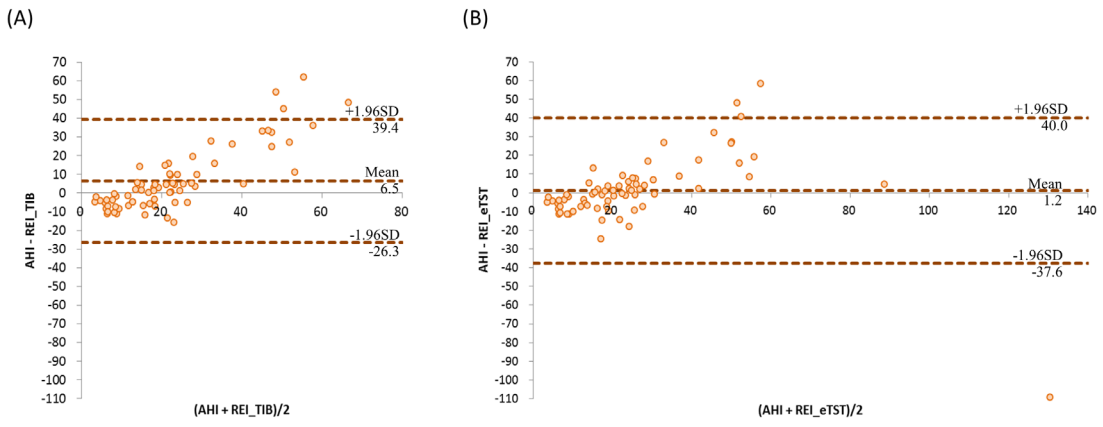

Figure 3. Bland-Altman plot for the apnea-hypopnea index (AHI) and respiratory event index (REI). (A) REI per hour of time in bed (REI_TIB) *vs*. AHI; **(B)** REI per hour of estimated total sleep time (REI_eTST) *vs*. AHI. Dotted lines represent the mean difference and the mean difference ± 1.96 standard deviation.

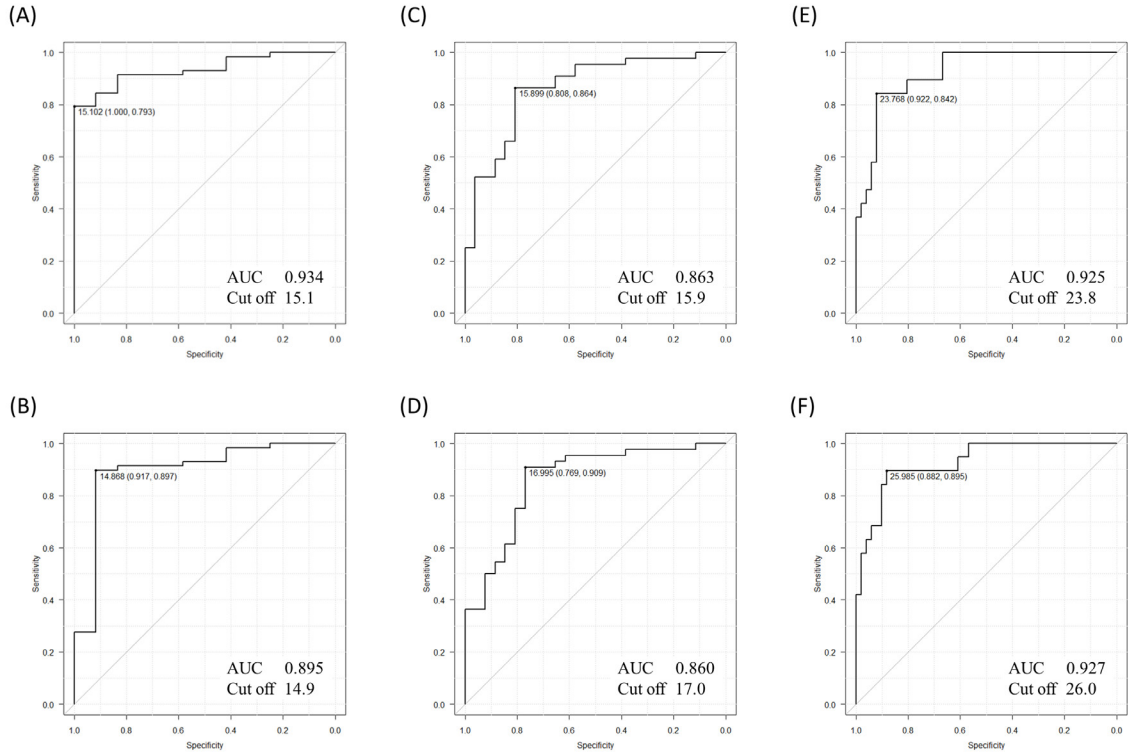

Figure 4. Receiver operating characteristic (ROC) curves of the respiratory event index (REI) for different apnea-hypopnea index (AHI) cut-off levels. (A) REI per hour of time in bed (REI_TIB) for AHI cutoff of 5; **(B)** REI per hour of estimated total sleep time (REI_eTST) for AHI cutoff of 5; **(C)** REI_TIB for AHI cutoff of 15; **(D)** REI_eTST for AHI cutoff of 15; **(E)** REI_TIB for AHI cutoff of 30; **(F)** REI_eTST for AHI cutoff of 30.

Table 2. Concurrent validity of the vibrometer-acquired respiratory event index for polysomnographically acquired apnea-hypopnea indexes of ≥ 5, ≥ 15, and ≥ 30

Variable	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	+LR	–LR	kappa
AHI≥5, REI_TIB≥15.1	79.3	100	100	50.0	–	0.21	0.57
AHI≥15, REI_TIB≥15.9	86.4	80.8	88.4	77.8	4.5	0.17	0.67
AHI≥30, REI_TIB≥23.8	84.2	92.2	80.0	94.0	10.7	0.17	0.75
AHI≥5, REI_eTST≥14.9	89.7	91.7	98.1	64.7	10.8	0.11	0.70
AHI≥15, REI_eTST≥17.0	90.9	76.9	87.0	83.3	3.9	0.12	0.69
AHI≥30, REI_eTST≥26.0	89.5	88.2	73.9	95.7	7.6	0.12	0.73

PPV: positive predictive value; NPV: negative predictive value; +LR: positive likelihood ratio; –LR: negative predictive likelihood ratio; Kappa: the kappa coefficient; AHI: apnea hypopnea index; REI: respiratory event index; REI_TIB: REI per hour of time in bed; REI_eTST: REI per hour of estimated total sleep time.

AHI ≥ 5 were 89.7%, 91.7%, and 0.70, respectively, whereas those for a REI_TIB of 15.1 as the cutoff value for predicting AHI ≥ 5 were 79.3%, 100%, and 0.57, respectively (Table 2). When the cutoff values of both REI_eTST and REI_TIB were set at 5 for AHI ≥ 5, the sensitivities, specificities, and kappa coefficients were found to be 100%, 8.3%, and 0.131, respectively. With regard to the prediction of AHI ≥ 15, the screening sensitivity, specificity, and kappa coefficient for REI_eTST of 17.0 as the optimal cutoff value were 90.9%, 76.9%, and 0.69, whereas those for REI_TIB of 15.9 as the optimal cutoff value were 86.4%, 80.8%, and 0.67, respectively. Moreover, with regard to the prediction of AHI ≥ 30, the sensitivity, specificity, and kappa coefficient for REI_eTST of 26.0 were 89.5%, 88.2%, and 0.73, whereas those for REI_TIB of 23.8 were 84.2%, 92.2%, and 0.75, respectively.

4. Discussion

In the present study, we aimed to evaluate the validity of SBV for OSA screening, while focusing on whether eTST could improve the consistency between AHI and REI. Therefore, we compared the screening accuracy of REI_eTST with that of REI_TIB according to the OSA severity cut-off levels. In particular, the sensitivity and specificity of non-wear PM devices for predicting severe OSA (AHI ≥ 30 events/h) have not been reported previously (*13-17*). However, in the present study, both REI_eTST and REI_TIB measured with the SBV

showed relatively high sensitivity and specificity at optimal cutoff values for predicting OSA with all three criteria (AHI ≥ 30, AHI ≥ 15, AHI ≥ 5), Moreover, data loss in PM recording using wearable sensors such as oronasal and respiratory effort sensors is considered an important problem (*11*). The fact that no data loss occurred during non-invasive SBV recording in the present study may be a valuable salient feature.

As reported previously, the REI_TIB is likely to be lower than the AHI in both type 3 and type 4 PM devices, which do not record the variables required for sleep stage scoring. In the present study, we also noted that the REI_TIB was significantly lower than the AHI. In contrast, there was no significant difference between the REI_eTST and AHI. In fact, the mean difference between the REI_eTST and AHI on Bland-Altman plots was also smaller than that between the REI_TIB and AHI. These findings suggest a somewhat beneficial feature of using REI calculation with eTST to reduce the difference between REI and AHI. However, this benefit may be limited by the accuracy of eTST, *i.e*., movement-based eTST, which can lead to TST overestimation when examinees do not move even when awake (*26*). In the present study, the underestimation of the event rate with REI_eTST with an increase in the AHI value appeared to reflect this phenomenon, as most of the patients with severe OSA exhibited TST overestimation (*18,20*).

In the present study, the optimal cutoff values for AHI ≥ 5 were approximately 15 episodes/h (14.9 for REI_eTST and 15.1 for REI_TIB) and were very close to those for AHI ≥ 15 (17.0 for REI_eTST and 15.9 for REI_TIB) despite relatively high sensitivity and specificity. Moreover, if the cutoff value was set at 5/h for both REI_eTST and REI_TIB, the specificities and kappa coefficients for predicting AHI ≥ 5 were clearly low with the 2 REIs. These results suggest that screening of AHI ≥ 5 with the SBV may be difficult, a problem that has been noted with wearable PMs (*12,27,28*). In contrast, when the REI value was set to 17.0 for REI_eTST or 15.9 for REI_TIB, the sensitivities and specificities for AHI ≥ 15 were good. Similarly, the 2 REI values for predicting AHI ≥ 30 had sufficient sensitivity and specificity. Thus, SBV was thought to be suitable for screening moderate-to-severe OSA, but was less acceptable for the screening of overall cases, including those with mild OSA (AHI ≥ 5).

The present study had certain limitations. First, the present study was conducted in a laboratory. In a study in which PSGs were conducted on different nights, 25% of individuals showed night-to-night variability of AHI greater than 20 events/hour (*29*). Considering this, we aimed to accurately evaluate the validity of SBV for OSA screening, using PSG-derived AHI on the same night in our laboratory as a reference. The 0% data loss and the screening ability could be partially attributable to this well-controlled environment. The data loss due to inaccurate device installation or forgetting to start the recording would possibly be greater during home recordings. Second, we scored apnea-hypopnea events using the AASM Chicago criteria, but did not use the AASM 2007 criteria (*30*) for PSG data. Ruehland *et al*. indicated that AHIs determined using the AASM Chicago criteria are significantly greater than those based on the AASM 2007 criteria (*31*). Thus, the screening ability of SBV could change if the AASM 2007 criteria are used. Future studies would be necessary to confirm the screening ability of SBV using AASM 2007 criteria.

In conclusion, SBV may be a clinically advantageous PM device due to the ability of REI to screen for moderate-to-severe OSA. REI_eTST showed a small but higher sensitivity and a relatively closer value to the AHI obtained *via* PSG as compared to REI_TIB. However, SBV appeared to be less acceptable for OSA screening in mild cases relative to moderate or severe cases. These characteristics should be confirmed in future home studies.

Acknowledgement

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Conflict of Interest

Takamasa Kogure is an employee of the company (PARAMOUNT BED CO., LTD.) that produces and distributes the sheet-shaped body vibrometer (NEMURI SCAN) used in this study.

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