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Accuracy Analysis of Embletta X100 for the Diagnosis of Obstructive Sleep Apnea and the Assessment of Sleep Structure

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Background and Objectives: To measure the accuracy of Embletta X100, a level 2 portable sleep monitoring device, for diagnosis of obstructive sleep apnea and assessment of sleep structure.

Materials and Method: We enrolled 200 consecutive patients who had been referred due to habitual snoring or witnessed apnea during sleep and had undergone standard polysomnography (PSG). We created a simulated situation similar to that of the Embletta X100 using only data from PSG and scored the sleep stage and the apnea-hypopnea index (AHI). Thereafter, the results of PSG and simulated Embletta X100 were compared.

Results: Sensitivity, specificity, and positive and negative predictive values of simulated Embletta X100 based on PSG were nearly 100% at three different cutoff values of AHI (5, 15, and 30). Intraclass correlation (ICC) of simulated Embletta X100 based on PSG was also excellent (≥0.9) for most of the sleep-related parameters and respiratory index. However, ICC of sleep stage percent was variable according to sleep stage (>0.9 for N1 and N2, 0.664 for N3, and 0.864 for R).

Conclusion: Although sleep staging is not very precise, Embletta X100 matches well with PSG overall.

KEY WORDS: Obstructive sleep apnea · Portable sleep monitoring · Embletta X100.

INTRODUCTION

Obstructive sleep apnea (OSA) is a highly prevalent sleep disorder characterized by repetitive upper airway collapse during sleep. OSA can cause various problems including daytime sleepiness, neurocognitive impairment, cardiovascular and metabolic disorders, and traffic accidents.[1)2)] The prevalence of OSA varies among studies, but it is presumed to be around 6−17% when OSA is defined as greater than 15 obstructive breathing events per hour during sleep.[3)] Moreover, the worldwide prevalence is believed to increase along with the global rise of obesity.[3)] Therefore, the demand for prompt detection of OSA patients is also increasing.

The gold standard for the diagnosis of OSA is polysomnography (PSG).[4)] However, it requires expensive equipment, an appropriate place, and qualified personnel, and therefore, the accessibility to PSG is extremely limited.[5)] To overcome these problems, many portable sleep monitoring devices have been developed. They are cost-effective and easy-to-use, and the tests of these devices can be conducted at home.[5)] At the beginning stage of development, the portable sleep monitoring devices were regarded as inaccurate and unreliable for detecting OSA.[6)] Recently, the devices have advanced rapidly and they are considered as an alternative to polysomnography under appropriate con-

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ditions.[5] However, most devices are classified as level 3 devices, which means that they cannot measure the sleep stage, but can only detect a breathing-related event. Therefore, level 3 devices consider total sleep time as the time elapsed until the patient turns the switch on and off for diagnosing OSA, and therefore, the apnea-hypopnea index (AHI) tends to be underestimated as the total sleep time increases.[5][6] Moreover, it is very important to determine the sleep quality for assessing OSA, especially judging the improvement after treatment, which is not possible with level 3 devices.[2][5][6]

Embletta X100 (Natus Medical Inc., San Carlos, CA) is an unattended 11-channel portable polysomnography device, which enables home-based testing without a technician and measures both the sleep stage and the breathing-related event simultaneously.[7] To increase convenience, in Embletta X100, the number of electroencephalography (EEG) channels has been decreased from 8 to 2 and only the nasal cannula is used excluding an oronasal thermal sensor.[7] If this level 2 device can accurately measure a breathing-related event and the sleep stage, the patient can receive convenient and inexpensive tests compared to conventional polysomnography and the physician can obtain almost all information from polysomnography, which will be beneficial to everyone. So far, there are few studies that have validated Embletta X100.[7][8]

The purpose of this study was to measure the accuracy of Embletta X100.

MATERIALS AND METHODS

This study was conducted at the Ajou University Hospital and it was approved by the internal review board (AJIRB-DEV-DE2-14-102). We reviewed medical records of 200 consecutive patients (>18 years of age) who had been referred to the Ajou University Hospital due to habitual snoring or witnessed apnea during sleep from January 2014 to June 2016 and had undergone standard PSG. There were no specific exclusion criteria.

PSG

PSG (Embla N 7000, Natus) was conducted and manually scored by a qualified sleep technician using analysis software (SomnologicaTM Studio 5.0, Embla, Broomfield, CO) according to the 2012 American Academy of Sleep Medicine guideline and the result was reviewed by a sleep specialist (HJ Kim): sleep montages for 8-channel EEG, electrooculography, electromyography (chin and leg), nasal airflow using a pressure cannula and oral flow measured by a thermistor, snoring assessed by a microphone situated in proximity to the thyroid cartilage, respiratory thoracic and abdominal efforts from plethysmography belts, trans-thoracic 2-lead ECG, and pulse oximetry were recorded.[4]

Simulated Embletta X100

All sensors, equipment and software used in the Ebletta X100 are exactly the same as the PSG used in this study. So, we did not directly use Embletta X100 in these patients; instead, we created a simulated situation similar to that of the Embletta X100 based on PSG data. More specifically, we imported previous PSG data into analysis software and hid some data including all EEG recordings, thermistor flow, snoring sound, leg electromyography, and ECG, and then, we derived a new EEG from C4 and O2 channels, which was a very similar situation to that created by Embletta X100. After the new setting was ready, the same sleep technician who performed PSG scored the sleep stage and the breathing-related event according to the 2012 American Academy of Sleep Medicine guideline. While scoring new data, the sleep technician was blinded to the result of PSG.

Data collection and statistical analysis

The parameters of sleep stage and breathing-related event were obtained from both PSG and Embletta X100. For evaluating the diagnostic accuracy of Embletta X100 in comparison with PSG, sensitivity, specificity, and positive and negative predictive values (PPV, NPV) were calculated at three different apnea-hypopnea index (AHI) cutoff values, namely 5, 15, and 30. For evaluating the agreement between PSG and Embletta X100, intraclass correlation (ICC) was calculated for various parameters and a Bland-Altman plot was constructed based on the AHI. Data were analyzed using a commercial statistical package (IBM SPSS statistics, version 23, Armonk, New York).

RESULTS

The demographic data of 200 patients is summarized in Table 1. The number of men (n=156) was higher than the number of women (n=44). Age, BMI, and sleep efficiency were not different between the two sexes; however, AHI

was much greater among men compared to women.

Diagnostic accuracy of simulated Embletta X100

Sensitivity, specificity, PPV, and NPV of simulated Embletta X100 based on PSG were nearly 100% at three different cutoff values of AHI, namely 5, 15, and 30. This result is summarized in Table 2.

Agreement between PSG and simulated Embletta X100

ICC

ICC of simulated Embletta X100 based on PSG was excellent ($\geq$0.9) for most sleep-related parameters (total sleep time, sleep efficiency, and wake time after sleep onset) and respiratory index (AHI, apnea index, hypopnea index, re-

Table 1. Demographics of patients

	Total (n=200)	Men (n=156)	Women (n=44)
Age (year)	39.6±14.4	39.2±13.9	40.9±16.0
BMI (kg/m^2)	25.7±3.8	25.7±3.5	25.7±4.9
Sleep efficiency (%)	83.5±11.5	83.8±11.7	82.4±11.1
Mean O_2 saturation (%)	95.5±2.0	95.4±2.1	96.0±1.5
Mean AHI	21.6±21.8	23.1±22.5	16.3±18.3
Distribution based on AHI severity			
AHI <5 (n)	50	34	16
5 ≤ AHI <15 (n)	50	38	12
15 ≤ AHI <30 (n)	50	43	7
30 ≤ AHI (n)	50	41	9

BMI: body mass index, AHI: apnea-hypopnea index, n: number

Table 2. Sensitivities, specificities, positive predictive values, and negative predictive values of simulated Embletta X100 according to different AHI cutoff values

Cutoff value	Embletta X100			
	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
AHI=5	100.0	98.0	99.3	100.0
AHI=15	99.0	99.0	99.0	99.0
AHI=30	100.0	99.3	98.0	100.0

AHI: apnea-hypopnea index, PPV: positive predictive value, NPV: negative predictive value

Table 3. Intraclass correlation between polysomnography and simulated Embletta X100

Variable index	ICC	95% confidence interval	p-value
Total sleep time	0.904	0.875–0.927	<0.001
Sleep efficiency	0.927	0.905–0.944	<0.001
Wake time after sleep onset	0.926	0.949–0.943	<0.001
Apnea-hypopnea index	0.972	0.964–0.979	<0.001
Apnea index	0.955	0.941–0.966	<0.001
Hypopnea index	0.978	0.971–0.984	<0.001
Respiratory disturbance index	0.914	0.888–0.934	<0.001
Central apnea index	0.948	0.932–0.961	<0.001
Mixed apnea index	0.972	0.963–0.979	<0.001
Respiratory arousal index	0.979	0.972–0.984	<0.001
Stage N1	0.933	0.912–0.949	<0.001
Stage N2	0.907	0.879–0.929	<0.001
Stage N3	0.664	0.579–0.735	<0.001
Stage R	0.864	0.824–0.895	<0.001

ICC: intraclass correlation coefficient

spiratory disturbance index, central apnea index, mixed apnea index, and respiratory arousal index). However, ICC of sleep stage percent was somewhat different according to the sleep stage. ICCs of stages N1 and N2 were more than 0.9, while ICCs of stages N3 and R were 0.664 and 0.864, respectively. This result is summarized in Table 3.

Bland-Altman agreement plot

Points were concentrated around the mean value of most parameters, while they were scattered more or less distant-

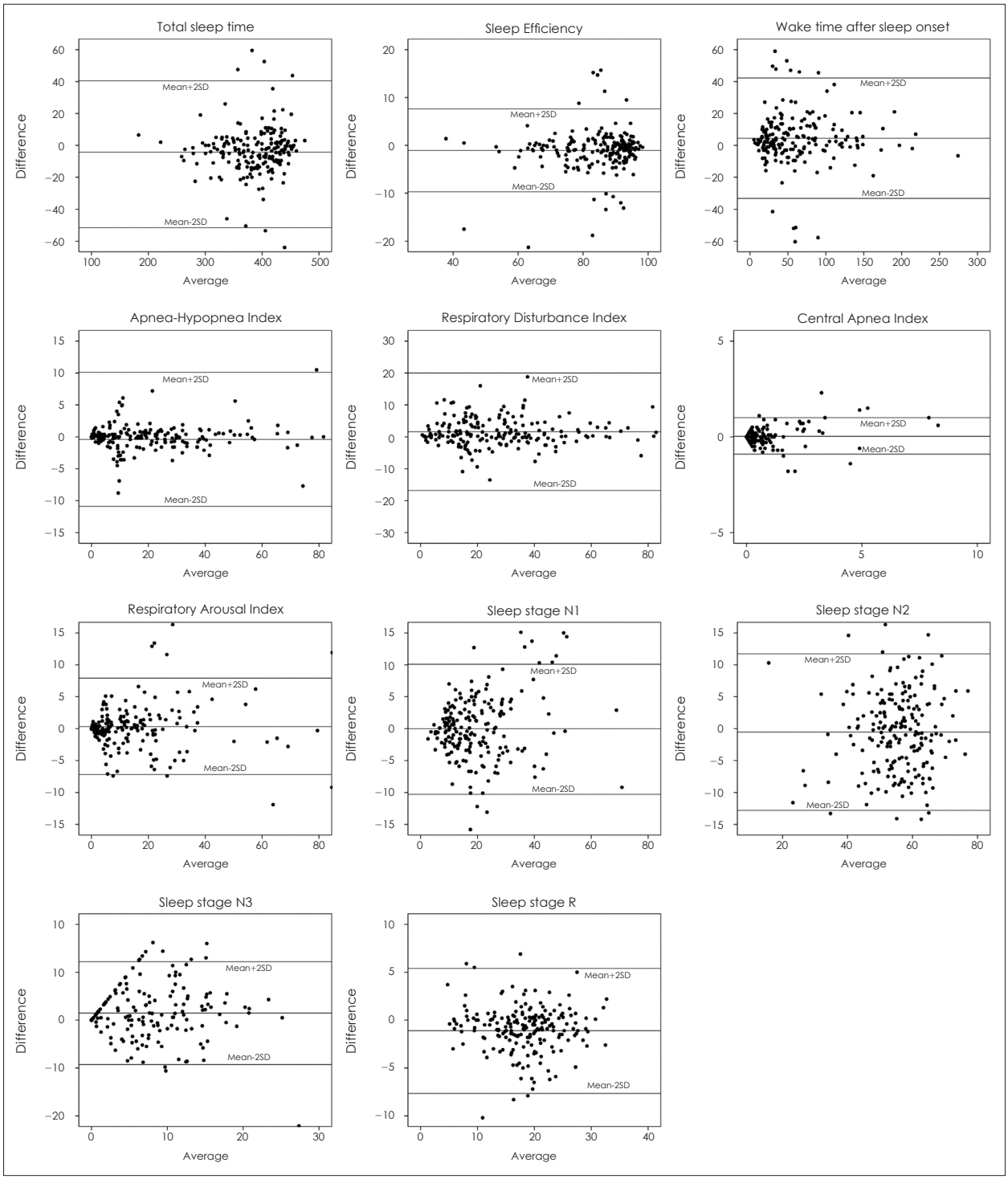

Fig. 1. Bland-Altman agreement plot for various parameters measured by standard polysomnography and simulated Embletta X100.

ly in Stages N3 and R (Fig. 1).

DISCUSSION

The most important aim of this study was to determine how accurately Embletta X100 can measure a breathing-related event and sleep stages using only two EEG sensors and a nasal cannula. In the absence of eight standard EEG sensors, it is difficult to pinpoint the main brainwaves that can determine the sleep stage.[9] This is because they are most frequently observed in different brain regions. In addition, accurate detection of apnea may be difficult without a thermistor.

In this study, the respiratory index was very accurately assessed by Embletta X100. ICCs for AHI, respiratory disturbance index, central apnea index, and respiratory arousal index were ≥0.9. The ICC of the apnea index was also very high, namely 0.955. However, the concordance rate of Stages N3 and R was relatively low. This suggests that Embletta X100 does not allow accurate detection of the slow wave, which is essential for determining stage N3. The slow wave is the strongest in the frontal derivation;[9] however, the frontal sensor is excluded from Embletta X100. It is also difficult to distinguish stage R determination from the slow eye movement of stage N1.[9] However, since the total sleep time is measured fairly accurately, it would be advantageous to calculate the respiratory index accurately compared to that obtained by level 3 devices. Chung et al. reported that the correlation coefficient of AHI between Embletta X100 and PSG was very high (0.972), while the correlation coefficients of stages N3 and R percentage were low (0.567 and 0.730, respectively).[8] In conclusion, Embletta X100 detects respiratory indexes very accurately, but it is less accurate for stages N3 and R sleep.

Embletta X100 provides an automated scoring system. In the previous study, we compared manual scoring and automatic scoring in 116 patients with OSA and we found that the correlation between these two scoring systems was very poor.[7] For example, correlation coefficients of total sleep time, stage R percentage, and AHI were 0.47, 0.054, and 0.761, respectively. Chung et al. also reported that the concordance rate of automatic scoring and PSG was very low.[8] Therefore, when using Embletta X100, scoring should be performed manually.

The biggest question in this study is whether the data obtained using PSG devices can actually be obtained using Embletta X100. In conclusion, it must be very similar. As the PSG device used in this study was made by the same manufacturer who built the Embletta X100, the performances of the basic body and the sensor are the same for both devices. Also, there is no difference in the analysis software as both devices use the same software. The greatest advantage of this analysis is that it completely prevents day-to-day variability. Because PSG testing is known to have significant day-to-day variability,[10][11] it is advisable to wear both devices simultaneously for accurate comparison. However, it is not possible to wear level 1 and 2 devices at the same time. Therefore, it is a good idea to use one device and reconstruct the results, as in this study.

Although this study was conducted under the supervision of the sleep technician in the hospital, the actual sleep test using Embletta X100 is performed at home, so there is a probability of test failure. According to Chung et al., only 2.3% of devices failed in an unattended environment and we also observed a failure rate of only 2.5% in our previous study.[7][8]

CONCLUSION

Although sleep staging is not very precise, Embletta X100 matches well with PSG overall. We think that it is an alternative which can be considered positively in an environment where PSG cannot be performed.

Acknowledgments

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