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Evaluation of a portable two-channel electroencephalogram monitoring system to analyze sleep stages

KANEMURA Takashi[1)], KADOTANI Hiroshi[1)], MATSUO Masahiro[1)], MASUDA Fumi[1)]
FUJIWARA Koichi[2)], OHIRA Masako[3)], YAMADA Naoto[1)]

携帯型2チャンネル脳波計を用いた睡眠段階解析の評価

加根村 隆[1)]，角谷 寛[1)]，松尾雅博[1)]，増田 史[1)]
藤原幸一[2)]，大平雅子[3)]，山田尚登[1)]

Objective: All-night polysomnography (PSG) is a useful tool for evaluating sleep quality. However, it requires subjects to sleep in an unfamiliar environment, which can influence sleep quality. Moreover, PSG is labor-intensive, time-consuming, and expensive. We evaluated a portable two-channel electroencephalogram (EEG) monitoring system and compared the signals obtained from the device with those of simultaneously recorded full PSG.

Methods: Signals obtained from two-channel EEG were comparing with simultaneously recorded full PSG signals. Sleep stages were scored using the American Academy of Sleep Medicine Manual for Scoring Sleep 2007. The epoch-by-epoch percent agreement and Cohen's kappa coefficient were used for agreement evaluation of sleep stage in both devices.

Results: The participants were healthy Japanese volunteers (mean (standard deviation): age: 20.9 (1.8) years; seven women and nine men). In epoch-by-epoch comparison, the average agreement and kappa value of sleep stages between two-channel EEG and PSG were 0.83 (0.04) and 0.75 (0.05), respectively. Kappa coefficients showed strong agreement for stage R (REM: rapid eye movement), stage W (wake), stage N3 (non-REM: NREM 3), and stage N2 (NREM 2) (0.86 (0.09), 0.76 (0.12), 0.74 (0.15) and 0.73 (0.06), respectively) and weak agreement for stage N1 (NREM 1) (0.44 (0.13)).

Conclusion: These results demonstrate that two-channel EEG facilitates home sleep monitoring and exhibits acceptable agreement with PSG. Therefore, this tool may be suitable for use in epidemiological and intervention studies.

Key words: electroencephalogram, home monitoring, portable device, sleep, two-channel electroencephalography
（脳波計，在宅計測，携帯型，睡眠，2チャンネル脳波計）

Introduction

Evaluation of sleep quality using all-night polysomnography (PSG) requires subjects to sleep in a medical facility. However, sleeping in a different environment can influence sleep quality[1-5]. Moreover, PSG is labor-intensive, time-consuming, and expensive[6]. Actigraphy is a simple method for monitoring locomotor activity and can be used to estimate sleep/wake time, but it cannot assess sleep architecture and sleep staging[7, 8].

Non-invasive long-term sleep monitoring at home or in nursing homes will become especially important in an aging society, as sleep changes occur with physical and mental disorders, and sleep disorders may affect health. Both physical and mental conditions significantly affect the quality of life of elderly subjects[9]. Recent advances in electronic technologies and sensor interfaces have enabled a significant reduction in the size and weight of recording equipment, resulting the development of a small EEG unit with only a few EEG electrodes[10, 11].

[1)] Department of Psychiatry, Shiga University of Medical Science, Shiga, Japan（滋賀医科大学精神医学講座）
[2)] Human Systems Laboratory Dept. of Systems Science, Kyoto University, Kyoto, Japan（京都大学大学院情報学研究科システム科学専攻）
[3)] Faculty of Education, Shiga University, Shiga, Japan（滋賀大学教育学部）

The objective of the present study was to validate the accuracy of a two-channel (2ch) EEG(ZA-9, Proassist, Ltd, Osaka, Japan) for sleep staging based on signals obtained from 2ch EEG by comparing its results with those of simultaneously recorded PSG, using the sleep staging criteria of the American Academy of Sleep Medicine (AASM) 2007 [12].

Methods

A. Participants

Twenty-two healthy students were recruited. All participants completed the following questionnaires: Epworth Sleepiness Scale (ESS) [13, 14], Insomnia Severity Index (ISI) [15, 16], and Patient Health Questionnaire (PHQ-9) [17, 18] on the day of PSG. The sleep stage signals as determined by PSG were compared with those simultaneously recorded by the 2ch EEG system. Sleep stages were manually scored using the American Academy of Sleep Medicine Manual for Scoring Sleep 2007 [12]. This study protocol was approved by the ethics committee of Shiga University of Medical Science.

B. Portable two-channel EEG monitoring system specifications

The portable ZA-9 EEG device (Proassist, Ltd, Osaka, Japan) consists of a receiver and a transmitter. The transmitter is 65mm(W) × 35mm(H) × 14mm(D), weighs 20 g, and is attached to the participant. The receiver is 35 mm(W) × 76mm(H) × 27mm(D), weighs 155g (**Figure 1**), and is placed in the examination room.

Disposable electrodes (**Figure 1**) (Blue Sensor M: Ambu A/S, Ballerup, Denmark) for channel 1 were placed 1cm above and slightly lateral to the outer canthus of the left eye and right mastoid. Another two disposable electrodes, for channel 2, were placed 1 cm below and slightly lateral to the outer canthus of the right eye as well as above the chin. The processing of the wave signal was as follows:

1. The analog wave signal was acquired by the transmitter.
2. The signal was sampled at 128Hz with a band-pass filter at 0.5–40Hz for channel 1 and 0.5–44Hz for channel 2 in the transmitter.
3. Analog-to-digital translation was performed at 12 bits in the transmitter.
4. The obtained analogue signal was transmitted to the receiver at 2.4GHz.
5. Data were stored in a European Data Format file on an SD card in the receiver.

Before scoring, we obtained two biological signals separated into four signals (an electroencephalogram with a 0.75–30Hz band-pass filter and a left electrooculogram with a 10Hz low-pass filter from channel 1, a right electrooculogram with a 10Hz filter, and a chin electromyogram with a 10–44Hz band pass filter from channel 2) by frequency band.

C. Overnight full PSG

A standard montage [12] was used for PSG recordings, including an electroencephalogram (EEG: C3/A2, C4/A1, O1/A2, O2/A1), electrooculogram (EOG: LOC/A2, ROC/A1), chin electromyogram (chin EMG), left and right anterior tibialis electromyogram (leg EMG), electrocardiogram (ECG), recording of snoring, oronasal pressure

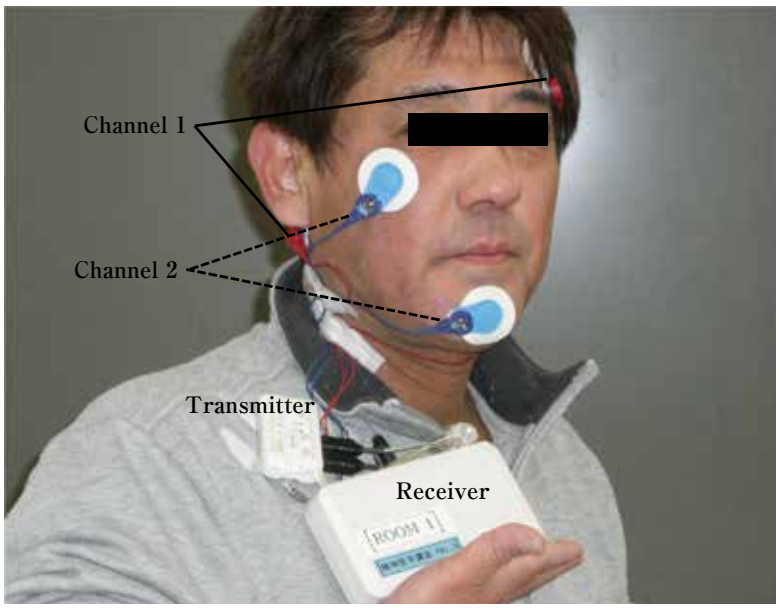

Figure1 The overview of 4 electrodes application and device including Transmitter and Receiver (ZA-9)

airflow, thoraco-abdominal effort, blood oxygen saturation (SpO_2, determined by pulse oximetry, and body position; Alice 5, Respironics, Inc., Murrysville, PA, USA).

D. Scoring

After data acquisition, the data were analyzed by a researcher blinded to the data sources—data files from the ZA-9 were randomly renamed by another staff member so that experimenters were blinded and concealed to the score. The time of analysis was the time between lights-out and lights-on for both the PSG and the ZA-9. All data were scored manually by one scorer, using the American Academy of Sleep Medicine Manual for Scoring Sleep 2007 [12]. The scoring software for the ZA-9 is SleepSign ver. 3.3 (Kissei Comtec, Nagano, Japan).

E. Statistical analysis

Categorical data are presented as proportions, and continuous data are presented as means and standard deviations (SD) or means and range. Pooled epoch-by-epoch agreement between the 2ch EEG system and PSG was established for sleep stages by calculating percent agreement and Cohen's kappa coefficient [19]. A kappa value of 0.00–0.20 is considered essentially no agreement, 0.21–0.40 low agreement, 0.41–0.60 moderate agreement, 0.61–0.80 high agreement, and 0.81–1.00 nearly perfect agreement [20]. Over all agreement and each stage agreements (W, N1, N2, N3, R) were calculated as follows:

A. Over all agreement:
   1. Classified each epoch by each sleep stage ("W", "N1", "N2", "N3", "R") into 5 × 5 cross table.
   2. Total number of epochs were scored as same stage ("W", "N1", "N2", "N3", "R") in both devices, was divided by total number of epochs.

B. Each stage agreement ("W", "N1", "N2", "N3", "R"):
   1. 5 × 5 cross table was modified to the 2 × 2 (object stage and others) cross table.
   2. Total number of epochs were scored as same stage (the object stage and others) in both devices, was divided by total number of epochs.

Statistical analyses were performed using SPSS for Windows release 15.0J (IBM, Armonk, NY).

Results

Participants were 12 men and 10 women. Their age (mean (SD: standard deviation)) was 21 (1.7) years. Body mass index was 20.6 (1.9) kg/m^2. The average and range (min–max) of Epworth Sleepiness Scale (ESS), Insomnia Severity Index (ISI), and Patient Health Questionnaire (PHQ-9) were 10.1 (6–16), 5.9 (0–14), and 2.1 (0–8), respectively.

Data from six of the 22 participants were excluded. We experienced technical difficulties with five datasets from the same ZA-9. Wave data from channel 1 had a very unstable baseline. Wave data baseline instability occurred suddenly and spread after a large electromyogram deflection. After replacing the device, this artifact did not appear on any channels. Therefore, we concluded that it was a technical difficulty related to this particular device. Data from one further participant was lost when the memory card came off the receiver when the participant turned over in bed. Thus, data from 16 participants (7 women, 9 men; age: 20.9 (1.8) years; body mass index: 20.7 (2.1) kg/m^2) were analyzed.

The wave forms from ZA-9 are shown in **Figure 2A–E**. Each wave form is recorded at 10mm/sec paper speed and 5 μV/mm sensitivity. Each vertical line represents 1 s. Four channels were used. The EEG_1 and EOG_1 signals were derived from the original channel 1 and EOG_2 and EMG_2 from the original channel 2. There was a 10–12Hz continuous alpha wave on EEG_1. The distribution of each wake and sleep stage is shown in **Table 1**. These parameters were very similar between PSG and ZA-9.

Other sleep variables determined by PSG were as follows: the average and range (minimum–maximum) of the arousal index (the total number of arousals per hour of sleep) was 8.8 (5.3–15.4), the apnea–hypopnea index (AHI: the total number of apnea and hypopnea occurrences per hour of sleep) was 0.3 (0.0–0.9), the CT90 (the cumulative time spent with SpO_2 below 90%) was 0.0 (0.0–0.0), the lowest SpO_2 was 93.4% (90.0–97.0%), and the periodic leg movement index (PLMI: periodic leg movements per hour of sleep) was 0.6 (0.0–2.0).

Epoch-by-epoch agreement and kappa values between ZA-9 and PSG for each stage are shown in **Table 2**. Individual agreement and kappa value **(Figure 3)** were 0.83 (0.04) and 0.75 (0.05), respectively. Kappa values showed strong agreement for stage R (REM: rapid eye movement), stage W (wake), stage N3 (non-REM: NREM 3), and stage N2 (NREM 2) (0.86 (0.09), 0.76 (0.12), 0.74 (0.15), and 0.73 (0.06), respectively) and weak agreement for stage N1 (NREM 1) (0.44 (0.13)). Nearly all the disagreement epochs for N1 were scored W or N2. The disagreement rates for N1 on the PSG were 32.5% (328/1,009) for N2 and 17.6% (178/1,009) for W on the ZA-9. In addition, the disagreement rates for N1 on the ZA-9 were 22.2% (173/779) for N2 and 21.1% (164/779) for W on the PSG.

Table 3 shows the pooled stage scoring results by epoch between PSG and ZA-9. The sensitivity of the ZA-9 for PSG staging was as follows: 0.77 for W, 0.42 for N1, 0.89 for

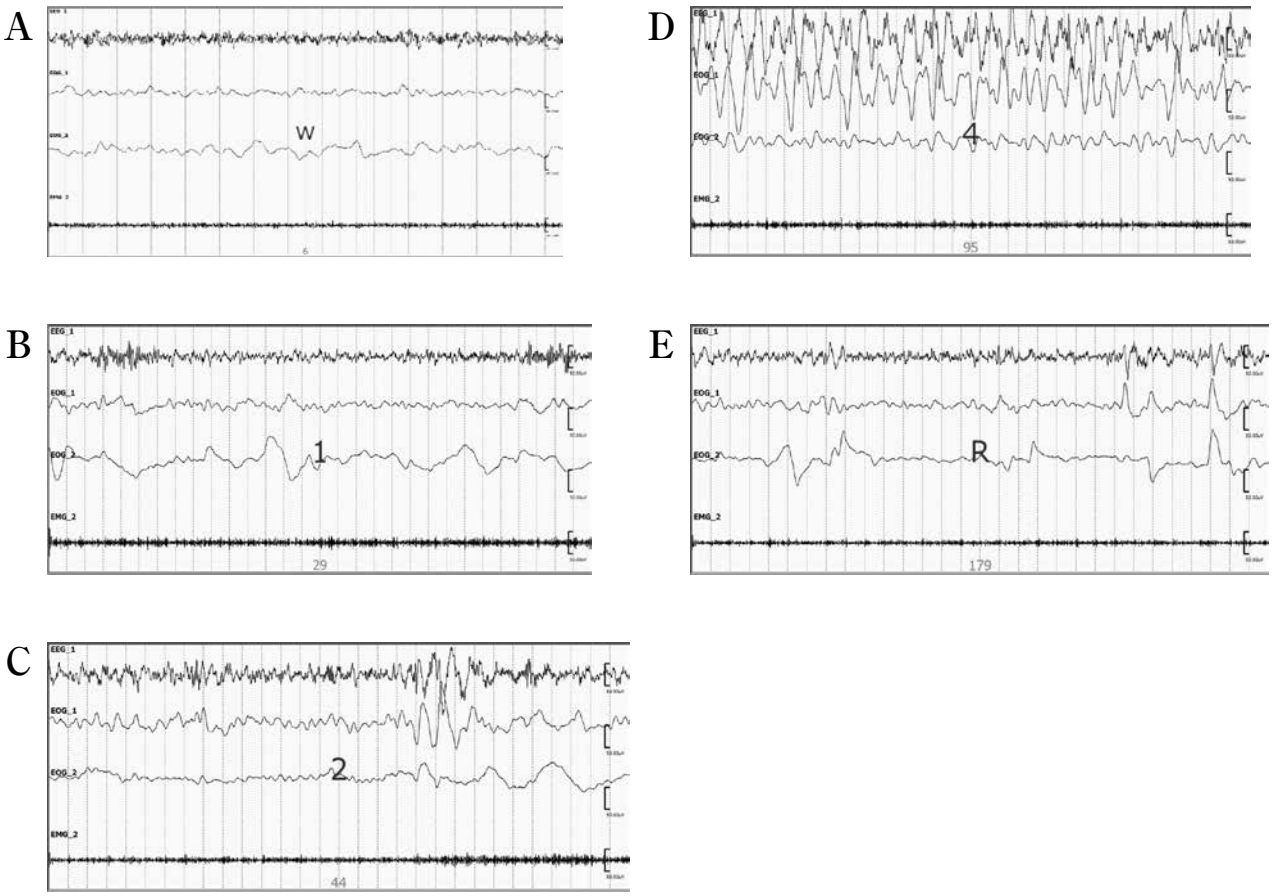

Figure 2 Representative raw wave forms obtained by two-channel electroencephalogram (ZA-9)

A, B, C, D, and E present samples of stage W (wake), R (rapid eye movement: REM), N1 (non-REM: NREM1), N2 (NREM2), and N3 (NREM3), respectively. The electroencephalogram (EEG), electrooculogram (EOG)_1, EOG_2, and electromyogram (EMG) are presented from the top to the bottom in each figure.

A: Stage W (wake). There was a 10-12Hz continuous alpha wave on EEG_1. The chin EMG amplitude was slightly low. B: stage N1 (NREM1). The beginning and ending of epoch show alpha waves. Between the two alpha waves, low-voltage and mixed-frequency and more than 50% are seen. C: stage N2 (NREM2). There are sleep spindles at 3-4s, middle, and 24-15s in the epoch. A high voltage exceeding 200μV is shown as a K-complex at the end of this epoch. D: Stage N3 (NREM3). High voltage waves exceed 20% of the epoch. The "4" in the middle of the epoch indicates stage 4 as per R & K criteria. E: Stage R (REM). Rapid eyes movements are shown in both EOG channels. Commonly, the eye movements are in phase. The background of the EEG wave is relatively low. The high voltage in the EEG waves is misclassified as eye movement. Here, the derivation cable on the same channel is shown in the same color and the movements are shown in-phase and out-of-phase.

Table 1 The distribution of sleep stages (n=16)

Devices	TIB(min)	SE(%)	%W	%N1	%N2	%N3
PSG	424 (4.5)	84.8 (11.4)	15.3 (11.5)	7.5 (3.0)	46.5 (10.5)	14.4 (4.4)
ZA-9	424 (4.5)	86.7 (10.2)	13.3 (10.3)	5.8 (3.4)	49.6 (9.7)	14.6 (6.7)

TIB: Total in Bed, SE: Sleep Efficiency, %: ratio to TIB. The values represent the average (standard deviation). W: wake. N1: non-REM (NREM) 1. N2: NREM2. N3: NREM3.

Table 2 Individual agreement and kappa value for each sleep stage by epochs (n=16)

Variables		Over all	W	N1	N2	N3	R
Agreement	average(SD)	0.83 (0.04)	0.88 (0.10)	0.58 (0.16)	0.83 (0.07)	0.83 (0.14)	0.86 (0.12)
	Min-Max	0.79－0.89	0.71－1.00	0.18－0.84	0.68－0.95	0.49－1.00	0.47－1.00
K value	average(SD)	0.75 (0.05)	0.76 (0.12)	0.44 (0.13)	0.73 (0.06)	0.74 (0.15)	0.86 (0.09)
	Min-Max	0.67－0.84	0.47－0.9	0.18－0.62	0.63－0.84	0.38－0.89	0.60－0.98

Agreement = Number of epochs, in which two-channel EEG and polysomnography scored the same sleep stage/Total number of epochs in the sleep stage defined by two-channel EEG.
SD: Standard deviation. W: wake. N1: NREM1. N2: NREM2. N3: NREM3. R: REM.

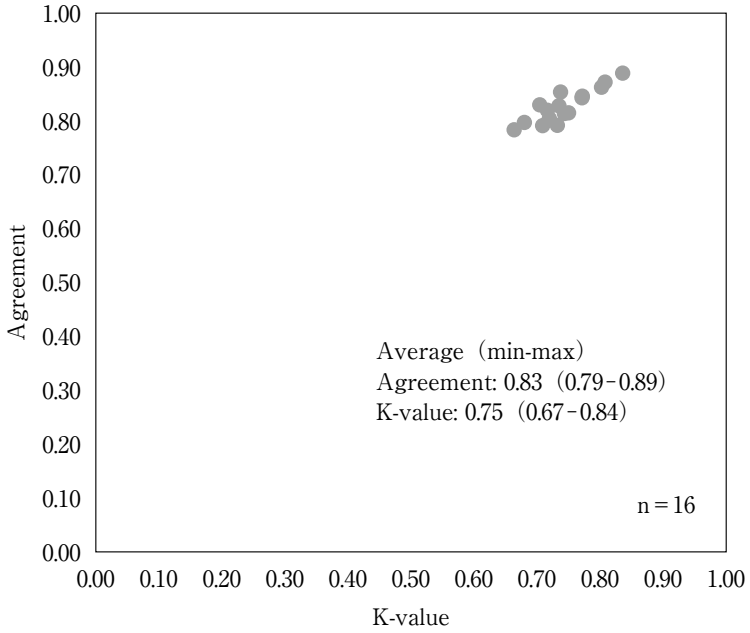

Figure 3 Scatter plots of Individual Agreements and K values by epochs

Data from a single individual are given for the same epochs for both PSG and ZA-9. Each spot represents agreement and a K-value of one night's sleep scoring data.

Y-axis: Scale of agreement, X-axis: Scale of K-value.

Table 3 Pair-wise epoch-by-epoch agreement between polysomnography (PSG) and two-channel EEG (ZA-9)

		PSG					
	Stages	W	N1	N2	N3	R	Total
ZA-9	W	**1,592**	178	12	2	11	1,795
	N1	164	**421**	173	0	21	779
	N2	185	328	**5,634**	388	190	6,725
	N3	24	15	348	**1,562**	0	1,949
	R	98	67	142	0	**2,001**	2,308
	Total	2,063	1,009	6,309	1,952	2,223	13,556

Table 4 Classified main reason and the types for disagreement regarding of staging in epochs

	Number (%)	Types
Carelessness	85 (36.0)	Human
High voltage EEG wave scoring	47 (19.9)	Device
Gap of time axis	28 (11.9)	Device
Artifact	14 (5.9)	Device
Mistake of share judgment	12 (5.1)	Human
Less spindles	8 (3.4)	Derivation
Overlooking α wave	8 (3.4)	Human
Overlooking Spindle	7 (3.0)	Human
Influence of sleep stages scoring at the previous epoch	5 (2.1)	Scoring rules
Less Slow wave	5 (2.1)	Derivation
No rapid eyes movements	5 (2.1)	Derivation
Overlooking βwave	4 (1.7)	Human
Overlooking K-Complex	3 (1.3)	Human
High voltage EEG wave scoring with EMG	2 (0.8)	Device
Unknown	2 (0.8)	Others
Less K-complex wave	1 (0.4)	Derivation
Total	236 (100.0)	

Table 5 Classification of the main reasons for disagreement on staging in epoch

Types	Number (%)
Human	119 (50.4)
Device specification	91 (38.6)
Derivation of channels	19 (8.1)
Scoring rules	5 (2.1)
Others	2 (0.8)
Total	236 (100.0)

N2, 0.80 for N3, and 0.90 for R. The positive-predictive value of ZA-9 for PSG staging was 0.89 for W, 0.54 for N1, 0.84 for N2, 0.80 for N3, and 0.87 for R.

Out of 13,556 epochs, 2,346 epochs (17.3%) were inconsistent between PSG and ZA-9 staging. We randomly selected 236 epochs out of these 2,346 epochs (10.1%), and reviewed these epochs to clarify the causes of these discrepancies (**Table 4**). Eighty-five (36.0%) were ascribed to carelessness (human error), 47 (19.9%) to high voltage EEG wave scoring (scoring rules), and 28 (11.9%) to gap of time axis (device) (**Table 4**). We reclassified the main reasons in Table 5, and subsequently ascribed 119 (50.4%) to human error, 91 (38.6%) to device specification, 19 (8.1%) to derivation of channels, 5 (2.1%) to scoring rules, and two (0.8%) to other reasons (**Table 5**).

Discussion

In this study, we compared 2ch EEG recordings with simultaneously recorded PSG in a sleep laboratory. The scoring results from the signals obtained from 2ch EEG agreed well with the manually scored PSG in sleep staging. Pooled sleep distribution is shown in **Table 1**. Sleep efficiency was slightly lower and the arousal index was slightly higher according to the PSG than according to the ZA-9. As participants slept in a different environment from their home, this was considered to reflect a first-night effect. The distribution of averages reported in previous research were based on data obtained over 2–7 nights [21]. There were no significant differences in the distribution of stages (%W, %N1, %N2, %N3, %R) between PSG and ZA-9 data. All variables (AHI, CT90, lowest SpO_2, and PLMI) were within normal limits.

The overall rate of agreement and kappa values from individual and pooled data were very high; similarly, the agreement and kappa values from individual and pooled data for each stage, except N1, were very high. Sensitivity and positive-predictive values were high for each stage, except for N1 (data not shown). Previous studies [22] have shown that agreement of scoring for N1 is generally low and varies widely, because there is no significant waveform on the EEG that can be used to score stage N1. A higher distribution of scoring for N1 may have decreased the agreement and kappa values. The average, minimum, and maximum time spent in stage N1 in this study were 33.0,

16.5, and 57.0 min, respectively. The correlation between kappa value and total time spent in stage N1 was −0.21. There was no correlation between lower kappa values and total time spent in stage N1 for cases with lower kappa values. The Kappa values were recalculated to compare the previous study [11] with 1ch EEG. The kappa values for "Overall", "Wake", "N1+N2" "N3" and "Rem" were 0.86, 0.80, 0.75, 0.77 and 0.86. "Wake" were similar, but "Overall", "N1+N2"and N3 were much higher. The reason why the kappa value in our study was high is thought as follows: In our study, 1) The high voltage slow wave (eye movement waveform on EEG channel and K complex) can be classified to some degree by the use of the left and light eye movements and the elevation of chin electromyogram, 2) A difficult N1 epochs to score and the N2 epochs were made the same category, 3) The distance of 2 electrodes for EEG derivation on channel 1 was longer (For N3), 4) A large number "N3" were able to be detected enough on ZA-9. Also, ZA-9 has two channel, it is possible to diagnose Sleep related Bruxism to record masseter muscle EMG. However, when the number of recording channels increases, electrodes application may become inconvenient for the participants.

Ten percent of the all discordant epochs were reviewed. "Carelessness," "High-voltage EEG wave scoring," and "Gap of time axis" were ranked as the top three of reasons for discrepant epochs. These epochs were then classified according to the type of main reason. Most were due to carelessness (human error), which reflects intra-rater variability. In previous studies [23-26], the agreement for "Wake", "Rem", "N2", "N3", and "N1" was 0.68−0.89, 0.78−0.94, 0.79−0.90, 0.69, and 0.23−0.74 respectively. Our intra-rater variability was similar to the inter-rater variability in a previous paper [27].

There may be some causes of differences, in epoch-by-epoch comparison between the ZA-9 and PSG. A number of "High voltage EEG wave scoring" and Gap of time axis may have contributed to the discrepancy. In the ZA-9, the EEG wave is obtained by a bipolar lead at the outer canthus of the left eye and the right mastoid. Eye movement can therefore easily contribute to the EEG, and may then be scored as a K-complex wave (the wave consist of bi- or tri-phasic sharp wave complex of 100−400 μV) [27]. An increase of chin EMG is admitted according to the generation of K-complex. When the waveform change can be confirmed, the agreement rate of EEG scoring may be improved. It is difficult to detect subtle changes in a chin EMG. The ZA-9 did not meet the AASM recommendation for EMG recoding. The EMG was recorded with the ZA-9 in a low sampling frequency of 128 Hz with 5μV/bit after filtered by high frequency filter (44Hz). AASM recommended digital specifications of EMG for full-PSG as sampling rate of minimum 200Hz and minimum digital resolution of 12bits per sample and high band-pass filter of 100Hz [12]. The high amplitude slow EEG waves contributed by both EEG channels are commonly in-phase, and eye movements are out-of-phase. The electrode cable for each channel is shown in the same color, which can lead to mistakes in placing electrodes. Filter settings and sampling rates may be modified to obtain better EMG waves.

The "Gap of time: axis" is a technical error and arises from the use of different clocks in the two devices. Before this validation, the change in the time axis was confirmed in the ZA-9. The discrepancy in the time axis was about 1−2 s and was clear. The internal time of PSG devices are adjusted by connection to the Internet at every study. However, the accuracy of the progress of time in the PSG device is unknown. It is difficult to keep the clocks of the two devices in sync for recording over a long period of time; this will remain a limitation for the validation of the two devices.

This study has some limitations. Participants were young healthy volunteers in a sleep laboratory. We have neither analyzed patients with sleep disorders nor performed home monitoring. PSG and ZA-9 data were analyzed by a single scorer. Further studies with simultaneously recordings of PSG and ZA-9 for sleep disorder patients and multicenter studies may be needed.

Conclusions

The 2ch EEG exhibits acceptable agreement with PSG and may facilitate home sleep monitoring. Therefore, this tool may be useful for the epidemiological studies and intervention studies.

Conflict of Interest

HK's laboratory is supported by donation from Philips Respironics GK, Takeda Pharmaceutical Company Limited, Sanofi K.K., and TEIJIN Limited to Shiga university of Medical Science and that he is a member of the Advisory Board for MSD K.K., Kyoto Industries Incubation Club and Sleepwell; doing collaboration work with TEIJIN Limited and Mizuno Corporation, Yamaha Corporation, Nippon Telegraph and Telephone Corporation, Sleepwell. TK, MM, FM, KF, MO and NY report no conflicts of interest.

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