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Revised manuscript

Validation of a single channel airflow monitor for screening of sleep-disordered breathing

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Single channel monitor for sleep apnea screening

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Abstract

Simple screening method for sleep-disordered breathing (SDB) is desirable for primary care practices. In the present study a simple monitor, which utilizes a new type flow sensor and a novel algorithm, was prospectively validated.

Two nights home recording with the monitor alone followed by in-laboratory recording with the monitor together with polysomnography were carried out in consecutive patients (n=100) suspected of SDB. A subjective sleep log was also recorded. The signal was analyzed using power-spectral analysis which yielded the respiratory disturbance index (flow-RDI).

There was no recording failure at home. The reproducibility of the flow-RDI between the two nights at home was high (intraclass correlation coefficient = 0.92). The sensitivity and specificity of the in-laboratory flow-RDI to diagnose SDB were 0.96 and 0.82, 0.91 and 0.82, and 0.89 and 0.96, for AHI \geq 5, \geq 15, and \geq 30, respectively. The diagnostic ability in low severity subgroups (female, normal-weight, AHI<15) was almost comparable to that in the entire group. Excluding subjective waking time on the sleep log from the recording time had no significant effect on the flow-RDI.

The single channel monitor is considered feasible for ambulatory SDB monitoring because of its easy applicability, high reproducibility and relatively high agreement with the polysomnography results.

Key words.

sleep apnea, screening, power-spectral analysis, thermal sensor

Introduction

Sleep-disordered breathing (SDB) is recognized as being very prevalent disease (1), which causes excessive daytime sleepiness resulting in impaired quality of life and increased risk of motor vehicle crashes. Moreover, SDB is considered as an independent risk factor for cardiovascular disease (2). It would therefore be desirable to perform a simple screening test for SDB in primary care practices for suspected patients or in health check-up for general population. Ordinary polysomnography (PSG) is a very time-consuming and labor-intensive process and it may not be applicable for this purpose. Although many kinds of portable monitors for SDB have been developed, the American Academy of Sleep Medicine has recommended only a "type 3" device under both the in-laboratory and attended conditions as an acceptable modality (3). The type 3 device incorporates at least 4 channels including two for respiratory movement and / or airflow, one for ECG or heart rate, and one for oxygen saturation. One of the most important problems for the ambulatory use of a type 3 monitor is data loss due to recording failure. For example, reported failure rates for type 3 home monitoring have been variously reported as 5.8% (4), 10% (5) and 18% (6). The set-up procedure for a type 3 device does not appear to be easy for many subjects. One study has compared the rate of recording failure between subjects with and without a sleep technician's setup at home (7% vs. 33%), indicating the necessity of the technician's assistance with the setup (7). We think a simpler method is desirable for SDB screening in primary care practices. Recently several single-channel airflow monitors have been developed for automated detection of SDB (8-10). These devices seem suitable for such a purpose. However, studies on the accuracy of these monitors have provided conflicting results. We think both analytic algorithm and flow sensor are crucial parts of such monitors. In this context, we have developed an algorithm to detect SDB from a single channel airflow record (11). The algorithm was tested using retrospective samples of airflow records from polysomnography and has been demonstrated to be relatively accurate and immune to noise contamination. However, validation of the algorithm in a real-life situation has not to date been performed. The primary aim of this study is to evaluate prospectively the performance of a single channel airflow monitor, which utilizes a new type flow sensor, combined with the analytic algorithm. An inevitable weakness of such a monitor is the inability to calculate real sleep time. We speculated that a subjective sleep log could help to overcome such a weakness, so an additional aim is to evaluate the usefulness of a subjective sleep log.

Methods

Subjects

This study was conducted in two hospitals. One was Fukuoka National Hospital (FNH), and the other was Tenri City Hospital (TCH). In each hospital, 50 consecutive patients who met the following inclusion criteria were invited to participate in this study. Inclusion criteria were patients referred for suspected sleep apnea, who were eligible to undergo diagnostic polysomnography and whose age was ≥18 and <65 years. The study protocol was approved by the Ethics Committee of both hospitals, and all participants gave written informed consent prior to the study.

Study protocol

The study consisted of recordings made on three consecutive nights. During the first and second nights, home recording was carried out with the portable monitor alone (Home-1, Home-2). During the third night, simultaneous recording with ordinary polysomnography and the portable monitor was performed in the hospital (Hosp). The subjects were asked to note subjective sleep time on a sleep log just after awaking in the morning (FNH: for all three night; TCH: for the two night at home). The subjects received the portable monitor at the first visit to the hospital, when a hospital technician made a brief instruction (about 5 minutes) about the method to attach the sensor to their face and operate the device. An instruction leaflet with the sleep log was also provided for the subjects.

Portable monitor

We used a single channel airflow monitor (SOMNIE, NGK sparkPlug Co. Ltd, Nagoya, Japan) as the portable monitor (Fig. 1). The SOMNIE utilizes a polyvinylidene fluoride (PVDF) film as the thermal sensor to detect airflow. The device stores the airflow signal as digital data at a sampling frequency of 10 Hz and has the capacity to record data for 24 hours. The airflow data can be reviewed if necessary (Fig. 2). The airflow sensor is designed to detect both nasal and oral breathing.

Polysomnography

PSG was recorded using a polygraph system (TCH: MME-3116; FNH: EEG7414, Nihon Kohden, Tokyo, Japan). Nasal airflow was monitored with a nasal prong pressure transducer (PTAF, Pro-Tec, Mukilteo, WA, USA). Nasal prongs were modified to be inserted into the nostrils so as not to interfere with the SOMNIE sensor that was attached below the nose. Thoracic and abdominal respiratory movements were monitored with respiratory inductive plethysmography (RIP; Respitrace, Ambulatory Monitoring Inc., Ardsley, NY, USA). Oxyhemoglobin saturation was monitored using a pulse oximeter (OLV-3100, Nihon Kohden, Japan) at the fastest response mode. The recording of the PSG and that of the SOMNIE were started at the same time.

Sleep stages were scored manually according to the standard criteria (12). The oxygen desaturation index (ODI) was defined by the number of SaO_2 -dips (\geq 3%) per hour of examination. Apnea was defined as an episode of clear airflow amplitude reduction (\geq 50%) lasting 10 seconds or longer, while hypopea was defined as an episode of discernible airflow amplitude reduction (< 50%) lasting 10 s or longer associated with a \geq 3% oxygen desaturation or an arousal according to the research definition of the American Academy of Sleep Medicine (13,14). The detection of apnea and hypopnea employed primarily airflow signal obtained by square root transformation of the nasal prong pressure. When the nasal pressure signal became inadequate (e.g. oral breathing), RIP sum signal amplitude reduction was used as the substitution. The scorers were blinded to the result of the SOMNIE. The apnea-hypopnea index (AHI) was calculated as the number of apnea and hypopnea events per hour of sleep.

Analysis

The data from the SOMNIE were analyzed automatically using a computer program(Flow.exe, Institute of Sleep Health Promotion, Tsukuba, Japan). It utilizes short time power spectral analysis and yields an index, the flow-respiratory disturbance index (RDI). The algorithm has been described in detail elsewhere (11). It is known that there is

a systematic bias between the flow-RDI and AHI which correlates to the AHI. Therefore, we used a cutoff value to diagnose SDB, which was determined from a regression analysis between the flow-RDI and AHI in a retrospective sample of PSG records including PVDF thermal flow sensor records. The cutoff value was 5.3, 11.4, and 19.6 for the SDBs of AHIs \geq 5, 15, and 30, respectively.

Reproducibility of the flow-RDI was evaluated using an intraclass correlation coefficient among the data from the three nights.

The relationship between the flow-RDI and the AHI was evaluated using Pearson's correlation coefficient. The agreement between these data was analyzed as described by Bland and Altman (15). The diagnostic ability of the flow-RDI for SDB was evaluated in terms of sensitivity and specificity. All the analyses were performed for each hospital separately and for the entire combined sample. The same analyses were performed for the ODI versus AHI relationship, and the relationship was compared between normal weight subjects (body mass index: BMI < 25) and over-weight subjects (BMI \geq 25). We also evaluated the diagnostic ability of flow-RDI for three subgroups of female subjects, normal weight subjects (BMI <25) and subjects with normal or mild SDB (AHI < 15).

In addition, to know whether a subjective sleep log is useful for improving diagnostic accuracy of the portable monitor, we performed the same analysis as described above for the SOMNIE's Home-1 data (n=25) and Hosp data (n=16) after excluding the subjective waking segment on the sleep diary in subjects whose subjective sleep time was less than 80% of recording time.

To evaluate event-by-event agreement, we compared the events detected by three methods of automated detection by the SOMNIE, visual inspection of the SOMNIE airflow record, and that of full PSG records, during mid one hour sleep in all cases. The event-by-event agreement was evaluated using the proportion of specific agreement (PSA) (16) As an estimate of clinical utility of the portable monitor, we investigated the relationship between the SDB severity by SOMNIE's Home-1 data and continual CPAP use at one year after the polysomnography. According to the Japanese medical insurance system, CPAP therapy was prescribed for the patients with AHI of ≥20 when they accepted the treatment. The data of the home monitoring were not taken into account for the decision of treatment.

Results

Patient characteristics are shown in Table 1. Their presenting symptoms included habitual snoring (n = 80), daytime sleepiness (n = 64), witnessed apnea (n = 63). There was no recording failure at all in either the home or in-laboratory studies. Their final diagnoses were obstructive sleep apnea hypopnea syndrome (n = 83), primary snoring (n = 12), insufficient sleep (n = 4), and depression (n = 1). No patients had significant periodic leg movement disorder.

Reproducibility of the flow-RDI

The intraclass correlation coefficients of the flow-RDI between the three nights were 0.92, 0.91 and 0.90, for Home-1 vs. Home-2, Home-1 vs. Hosp and Home-2 vs. Hosp, respectively, in FNH, whereas in TCH they were 0.91, 0.86 and 0.88, respectively, and were 0.92, 0.88 and 0.89, respectively, for all subjects

Agreement between the AHI and flow-RDI (Table2)

The correlation coefficient between the AHI and flow-RDI at Hosp was 0.94(95% confidence interval: CI 0.91-0.96), while that between the AHI at Hosp and flow-RDI at Home-1 was 0.84(CI 0.77-0.89), for combined data. The Bland and Altman analysis showed that the mean difference between the flow-RDI and the AHI at Hosp was -9.5 (95% agreement limit: -30.4 to 11.4; Fig. 3A). The relatively wide difference is thought to be largely due to the difference in the denominator (examination time vs. sleep time) because the difference between the flow-RDI and apnea-hypopnea number per hour of examination was far narrower (mean -1.2; 95% agreement limit:-12.9 to 10.6; Fig. 3B).

Diagnostic ability of the flow-RDI (Table2)

The diagnostic sensitivity and specificity values of the flow-RDI to identify patients with three different AHI thresholds (≥ 5 , ≥ 15 , ≥ 30) ranged between 0.89-0.96 and 0.82-0.96, respectively, for the concurrent study with PSG (Hosp). The negative likelihood ratio ranged between 0.05-0.12. The overall diagnostic ability as expressed by the area under the receiver operating characteristic curve was 0.95-0.98.

Comparison with the oximetry analysis

The correlation coefficient between the ODI and AHI was 0.95 and the mean difference between the ODI and the AHI was -9.3 (95% agreement limit: -29.2 to 10.6), which were equivalent to those between the flow-RDI and AHI. However, the correlation between the ODI and AHI was worse in normal weight subjects than that in overweight subjects (Fig. 4). By contrast, the correlation between the flow-RDI and AHI was not affected by the body habitus. In addition, in the subjects with AHI less than 30, the difference between the flow-RDI and AHI was narrower than that between the ODI and AHI (Fig. 5).

Evaluation of flow-RDI in low severity subgroups (Table 3)

We used three subgroups of female, normal-weight subjects and subjects with AHI less than 15 for this analysis. The AHI tended to be lower in the three subgroups. The difference between the flow-RDI at Hosp and the AHI was narrower in all subgroup subjects than in the subjects taken as a whole. The diagnostic ability of the flow-RDI in each subgroup was almost comparable to that of all subjects taken together.

Utility of the subjective sleep log on portable monitoring

The correlation coefficient between the AHI at Hosp and the flow-RDI at Home-1 was 0.78 and 0.79 before and after excluding subjective waking time, respectively. The mean difference between the AHI and flow-RDI was -11.7 (SD 18.4) both for before and after excluding subjective waking time. The correlation coefficients between the AHI and the concurrent flow-RDI at Hosp were 0.94 and 0.97 before and after excluding subjective waking time, respectively. The mean differences between the AHI and flow-RDI were -10.3 (SD 11.6) and -8.9 (9.2) before and after excluding subjective waking time, respectively. The correlation coefficient between subjective sleep efficiency as assessed by the sleep log and actual sleep efficiency by PSG was 0.41 (n=48).

Event-by-event analysis

The analysis of event-by-event agreement showed that the SOMNIE automated and manual analysis detected 79 % and 74 % of apnea/hypopnea events detected by the full PSG analysis, respectively. The ratio of number of false positive events to that of total events detected by the SOMNIE was 9% and 7% for automated and manual analysis, respectively. The PSA between the PSG analysis and the SOMNIE analysis was 0.84, while that between the PSG analysis and the SOMNIE manual analysis was 0.83. The PSA between the SOMNIE automated and manual analyses was 0.92.

Result of home monitoring and CPAP use after one year

CPAP treatment was prescribed for 42 patients, out of which 32 patients continued to use it for at least one year. The relationship between the SDB severity by the SOMNIE's Home-1 data and continual CPAP use was as follows: normal 14 patients (CPAP use 0), mild SDB 22 patients (CPAP use 1), moderate SDB 21 patients (CPAP use 3) and severe SDB 43 patients (CPAP use 28).

Discussion

The single channel portable monitor used in the present study provided the flow-RDI which had a relatively high agreement with the AHI assessed with the concurrent PSG record. The event-by-event agreement between the two methods was also good. The flow-RDI was reproducible for two nights at home. There was no recording failure for the home monitoring. These results suggest the portable monitor with the automatic analysis program is feasible in ambulatory screening for SDB.

The flow-RDI tended to be lower than the concurrent PSG AHI value. This difference is considered to be predominantly due to the fact that the denominator of flow-RDI was recording time while that of the AHI was sleep time, because there was very little difference between the flow-RDI and apnea / hypopnea number per hour of recording. To overcome the weakness of flow-RDI, we used cutoff values for the flow-RDI to detect SDB, and as a result high diagnostic sensitivity was obtained. We also tried to utilize the subjective sleep log to exclude waking time from the record for analysis. The agreement between the flow-RDI and concurrent AHI was only slightly better after excluding subjective sleep time than before excluding it. However, this procedure had no effect at all on the agreement between the flow-RDI at home and the AHI at hospital. The fact means that the effect of waking time during home monitoring is far more trivial as compared with the night-to-night variability of SDB severity.

There have been three single channel airflow monitors for which data about agreement with simultaneously recorded PSG have been published in the literature. Two monitors utilize a nasal pressure sensor (9,10), and the other utilizes a thermistor (8). The correlation coefficient between the portable monitor-derived index and PSG-derived AHI was 0.80 (10) and 0.89 (9) for the two monitors utilizing the nasal pressure sensor, whereas it was 0.73 for the monitor utilizing the thermistor (8). The diagnostic ability expressed as the area under the receiver operating characteristic curve for detection of the case with an AHI of 5 or more was 0.89 (10) and 0.86 (9) for the two monitors utilizing the nasal pressure sensor. The present study showed the correlation coefficient was 0.94 and the area under the receiver operating characteristic curve was 0.95, demonstrating equivalent or superior agreement with PSG as compared with the portable monitors utilizing the nasal pressure sensor.

Another modality of single channel monitoring is oximetry alone. There are many reports about the diagnostic ability of this method. Some studies have shown very good diagnostic ability of oximetry alone (17, 18). However, this method is known to have a drawback in that the results are affected by the subjects' body habitus (19). The present study demonstrated that the agreement of oximetry-derived index (ODI) with the AHI was worse in normal weight subjects than in overweight subjects but it was not the case for the flow-RDI.

We think the crucial parts of portable monitors for accurate detection of SDB are the airflow sensor and the algorithm to detect breathing events. Conventional thermal sensors are known to have a tendency to overlook hypopnea events and are considered inadequate for sleep study (20). The portable monitor in this study utilized a PVDF film. Recently, Berry et al have reported that the PVDF airflow sensor had excellent ability to detect hypopnoea (21). Regarding the analytic algorithm, we used the newly developed algorithm for single channel airflow monitors. We have demonstrated that the algorithm was applicable to different types of sensors including thermocouple, nasal pressure and PVDF sensors and was relatively immune to noises and change in sensitivity during long time recording (11). We believe that the high ability of the sensor and the robustness of the algorithm are the reasons for the observed high accuracy and reproducibility of the portable monitor used in the present study.

Several limitations in this study must be addressed. The subjects studied were patients referred for suspected sleep apnea and not subjects from the general population. Therefore, the findings in this study may not be applicable to the general population. The subjects in the present study might have been better motivated to perform the home monitoring than members of the general population, which may be the reason for no recording failure. Furthermore, the subjects had different characteristics from a cross section of the general population, being predominantly male, and having a higher than average BMI. Therefore, we examined the diagnostic ability of the flow-RDI in subgroups of female subjects and normal-weight subjects. The results showed the diagnostic ability in such subgroups was similar to that of all of the subjects taken together. Another problem is that the subjects' average AHI was far greater than that of SDB subjects in the general population. This fact could be a reason for the high diagnostic sensitivity of the flow-RDI in the present study. To exclude this possibility, we also examined the diagnostic ability of the flow-RDI in subjects with AHI less than 15, as a result of which the flow-RDI was shown to have a relatively high diagnostic ability even in this low severity subgroup. Although an exact validation in a cross-section of the general population remains to be performed, these facts might suggest that the portable monitor can be used for screening of SDB from a variety of populations. The other important problem is the effect of sleep efficiency. The mean sleep efficiency of the subjects in the present study was relatively high. If low sleep efficiency subjects (e.g. patients with insomnia) are tested, the agreement between the flow-RDI and AHI could be quite different from that of the present study.

Finally, the issue of clinical utility of the device should be addressed. The most possible usage of the single channel monitor is thought to be case finding in primary care practices. Many of subjects in this study were referred for the symptom of habitual snoring without overt sleepiness, which can be underestimated by the subjects suffering from long-standing sleep disturbance (22). In a study in primary care settings, 37.5% of the patients were identified as being in a high risk group of sleep apnea syndrome (23). It

seems somewhat difficult to perform polysomnography in all of such patients. Thus, ambulatory screening using a portable monitor in this group is thought to be a practical way to determine candidates for polysomnography. In the present study, 31 out of 32 patients continuing to use CPAP at one year after the diagnosis had the home monitoring data corresponding to moderate to severe SDB, which means the portable monitor could screen for candidates for CPAP therapy. Home monitoring also has the possible advantage that subjects can undergo the screening test in their usual sleep environment because sleep position and alcohol drinking can affect the subjects' SDB severity (24). It is also very important to recognize that the single channel monitor does not evaluate sleep and it has no ability to detect other sleep disorders than SDB. Therefore, patients with a negative result and unexplained severe sleepiness should be referred to sleep specialists.

In conclusion, the single channel airflow monitor is easily applicable at home and relatively accurate. These advantages are thought to be due to both the high performance sensor (PVDF) and the robust analytic algorithm. We believe this method can be applicable in screening for SDB in primary care practices.

References

- 1. Young T, Palta M, Dempsey J, Skatrud J, Weber S, Badr S. The occurrence of sleep-disordered breathing among middle-aged adults. N Engl J Med 1993; 328: 1230–1235.
- 2. McNicholas WT, Bonsignore MR and the Management Committee of EU COST ACTION B26. Sleep apnoea as an independent risk factor for cardiovascular disease: current evidence, basic mechanisms and research priorities. Eur Respir J 2007; 29: 156–178.
- 3. A joint project sponsored by the American Academy of Sleep Medicine, the American Thoracic Society, and the American College of Chest Physicians. : Practice parameters for the use of portable monitoring devices in the investigation of suspected obstructive sleep apnea in adults. Sleep 2003; 26:907–913.
- 4. Verse T, Pirsig W, Ising BJ-H, Kroker B. Validation of the POLY-MESAM seven-channel ambulatory recording unit. Chest 2000; 117:1613–1618.
- 5. Parra O, García-Esclasans N, Montserrat JM, L. Eroles G, Ruíz J, López JA, Guerra JM, Sopeña JJ. Should patients with sleep apnoea/hypopnoea syndrome be diagnosed and managed on the basis of home sleep studies? Eur Respir J 1997; 10: 1720–1724.
- 6. Dingli K, Coleman EL, Vennelle M, Finch SP, Wraith PK, Mackay TW, Douglas NJ. Evaluation of a portable device for diagnosing the sleep apnoea/hypopnoea syndrome Eur Respir J 2003; 21: 253–259.
- 7. Golpe R, Jiménez A, and Carpizo R. Home sleep studies in the assessment of sleep apnea/hypopnea syndrome Chest 2002; 122: 1156–1161.
- 8. Shochat T, Hadas N, Kerkhofs M, Herchuelz A, Penzel T, Peter JH, Lavie P. The SleepStrip: an apnoea screener for the early detection of sleep apnoea syndrome. Eur Respir J 2002; 19: 121–126.
- 9. Erman MK, Stewart D, Einhorn D, Gordon N, Casal E. Validation of the ApneaLink for screening of sleep apnea: a novel and simple single-channel recording device. J Clin Sleep Med 2007;3:387–392.
- 10. de Almeida FR, Ayas NT, Otsuka R, Ueda H, Hamilton P, Ryan FC, Lowe AA. Nasal pressure recordings to detect obstructive sleep apnea. Sleep Breath 2006; 10: 62–69.
- 11. Nakano H, Tanigawa T, Furukawa T, Nishima S. Automatic detection of sleep-disordered breathing from a single-channel airflow record. Eur Respir J 2007; 29: 728–736.

- 12. Rechtschaffen A, Kales A. A manual of standardized terminology, techniques and scoring systems for sleep stages of human subjects. National Institute of Health, Publ. No.204, Public Health Service, Government Printing Office, Washington DC, 1968.
- 13. Kushida CA, Littner MR, Morgenthaler T et al. Practice parameters for the indications for polysomnography and related procedures: An update for 2005. Sleep 2005;28:499–521.
- 14. Bonnet M, Carley D, Carskadon M, Easton P, Guilleminault C, Harper R, Hayes B, Hirshkowitz M, Ktonas P, Keenan S, Pressman M, Roehrs T, Smith J, Walsh J, Weber S, Westbrook P. EEG arousals: scoring rules and examples: a preliminary report from the Sleep Disorders Atlas Task Force of the American Sleep Disorders Association. Sleep 1992; 15:173–184.
- 15 Bland JM, Altman DG. Statistical methods assessing agreement between two methods of clinical measurement. Lancet 1986; 1: 307–310.
- 16. Fleiss JL. Statistical methods for rates and proportions. New York, John Wiley & Sons, 2003; pp. 599–608.
- 17. Vázquez JC, Tsai WH, Flemons WW, Masuda A, Brant R, Hajduk E, Whitelaw WA, Remmers JE. . Automated analysis of digital oximetry in the diagnosis of obstructive sleep apnea. Thorax 2000;55:302–307.
- 18. Gurubhagavatula I, Maislin G, Pack A. An algorithm to stratify sleep apnea risk in a sleep disorders clinic population. Am J Respir Crit Care Med 2001; 164: 1904–1909.
- 19. Nakano H, Ikeda T, Hayashi M, Ohshima E, Itoh M, Nishikata N, Shinohara T. Effect of body mass index on overnight oximetry for the diagnosis of sleep apnea. Respir Med 2004; 98: 421–427.
- 20. Farre R, Montserrat JM, Rotger M, Ballester E, Navajas D. Accuracy of thermistors and thermocouples as flowmeasuring devices for detecting hypopnoeas. Eur Respir J 1998; 11: 179–182.
- 21. Berry RB, Koch GL, Trautz S, Wagner MH. Comparison of respiratory event detection by a polyvinylidene fluoride film airflow sensor and a pneumotachograph in sleep apnea patients. Chest 2005; 128: 1331–1338.
- 22. Hans P.A. Van Dongen HP, Maislin G, Mullington JM, David F. Dinges DF. The cumulative cost of additional wakefulness: dose-response effects on neurobehavioral functions and sleep physiology from chronic sleep restriction and total sleep deprivation. Sleep 2003;26:117–26.
- 23. Netzer NC, Stoohs RA, Netzer CM, Clark K, Strohl KP. Using the Berlin questionnaire to identify patients at risk for the sleep apnea syndrome. Ann Intern Med 1999;131:485–491.

24. Tanigawa T, Tachibana N, Yamagishi K, Muraki I, Umesawa M, Shimamoto T, Iso H. Usual alcohol consumption and arterial oxygen desaturation during sleep. JAMA 2004; 292:923–925.

Table 1. Subject characteristics

Hospital	FNH	TCH
No.	50	50
Gender male/female	40/10	40/10
Ageı y.o.	44.2±10.6	46.3±10.7
Body mass index	26.4±4.1	27.4±4.4
AHIı /hr	27.4(9.5-47.6)	33.6(123-65.2)
ODI ₁ /hr	15.8(5.8-36.4)	25.8(8.3-41.3)
Sleep efficiency, %	80.9±10.7	76.3±11.9
No. of patients with AHI		
≥5/hr₁ n(%)	44(88)	45(90)
≥15/hr₁ n(%)	30(PO)	35(70)
≥30/hr₁ n(%)	24(48)	28(5L)
Flow-RDI, Home l, /hr	14.2(8.5-32.9)	16.3(8.4-31.9)
Flow-RDI, Home 2, /hr	15.1(8.6-37.5)	15.7(7.8-36.1)
Flow-RDI: Hosp: /hr	16.5(8.8-36.0)	22.9(10.3-45.1)

Data are presented as mean±SD, median (interquartile range), or n (%).

AHI: apnoea/hypopnoea index; ODI: oxygen desaturation index at the threshold of 3%;

RDI: respiratory disturbance index.

Table 2 Agreement between the in-laboratory flow-RDI and AHI

		FNH	TCH	A11
No-		50	50	700
	on between			
AHI and f	low-RDI			
	r	0.95	0.93	0.94 (0.91-0.96)
Differenc	e between			
AHI and f	low-RDI			
	Mean	-8.2	-10.8	- 9.5
	ZD	9.1	12.0	10.7
Diagnosti flow-RDI	c ability of			
AHI>5	sensitivity	0.96	0.96	0.96 (0.91-1.00)
	specificity	0.83	0.80	0.82 (0.59-1.00)
	P-LR	5.7	4 - 8	5.3 (2.4 - 11.7)
	N-LR	0.05	0.06	0.05 (0.03 - 0.09)
	AUC	0.94	0.95	0.95 (0.90-0.99)
AHI>15	sensitivity	0.90	0.91	0.91 (0.84-0.98)
	specificity	0.90	0.73	0-82 (0-70-0-95)
	P-LR	8.6	3.4	5.2 (3.9 - 6.8)
	N-LR	0.77	0.12	0.11 (0.08-0.15)
	AUC	0.97	0-94	0.96 (0.92-0.99)
OE <iha< td=""><td>sensitivity</td><td>0.83</td><td>0.93</td><td>0.89 (0.80-0.97)</td></iha<>	sensitivity	0.83	0.93	0.89 (0.80-0.97)
	specificity	0.92	1.00	0.96 (0.90-1.00)
	P-LR	10.8	NA	21.2 (8.3-54.6)
	N-LR	0.18	0.07	0.12 (0.09-0.16)
	AUC	0.96	0-99	0.98 (0.94-1.00)

95% confidence interval in parentheses; r: Pearson's correlation coefficient; AHI: apnoea/hypopnoea index; RDI: respiratory disturbance index; AUC: area under the receiver-operating characteristic curve; P-LR: positive likelihood ratio; N-LR: negative likelihood ratio

Table 3 Evaluation of in-laboratory flow-RDI in subgroups

	A11	Female	BMI<25	
No-	100	50	36	
AHI	31.2(10.3-54.9)	12.0(7.5-22.3)	15.3(6.6-33.2)	B
Correlation between Alflow-RDI	HI and			
r	0.94	0.90	0.93	
Difference between AH flow-RDI	I and			
Mean	-9.5	-5.3	-5.1	
ZD	10.7	10.2	8.0	
Diagnostic ability of flow-RDI				
AHI>5 sensitivi	ity 0.96	0.88	0.97	
specifici	ity 0.82	0.67	0.71	
AUC	0.95	0.88	0.94	
AHI>15 sensitivi	ity 0.91	0.75	0.78	
specifici	ity 0.82	0.83	0.89	
AUC	0.96	0.89	0.92	
AHI>30 sensitivi	ity 0.89	1.00	0.91	
specifici	ity 0.96	0.94	0.92	
AUC	0.98	1.00	0.97	

AHI: apnoea/hypopnoea index (median and interquartile range); RDI: respiratory disturbance index; r: Pearson's correlation coefficient; AUC: area under the receiver-operating characteristic curve; BMI: body mass index

Legends for figures

Fig. 1 The single channel monitor "SOMNIE"

A. The SOMNIE disposable sensor attached below the nose. B. The recording device. C.

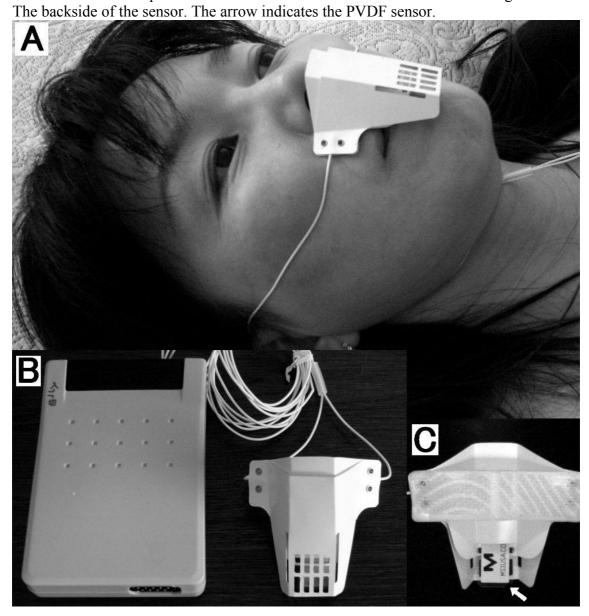


Fig. 2 Example of respiratory signal waveforms from polysomnography and simultaneous SOMNIE record. The nasal pressure was square root transformed. One apnea and one hypopnea events are shown.

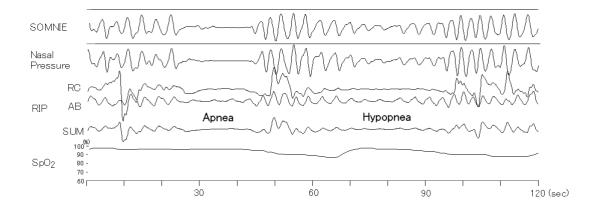
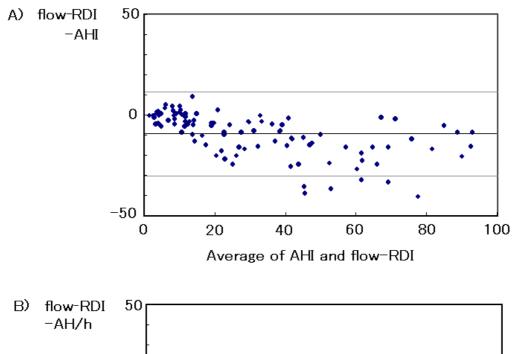


Fig. 3 Bland & Altman plots
Difference between the flow-RDI determined by the in-laboratory SOMNIE and apnea-hypopnea index (AHI) determined by the simultaneous polysomnography was plotted against the average value of the two methods. In (A) ordinary AHI (per hour of sleep) was used, while in (B) apnea hypopnea number per hour of recording (AH/h) was used instead. Black lines indicate the mean difference, and the grey lines indicate the 95% limit of agreement.



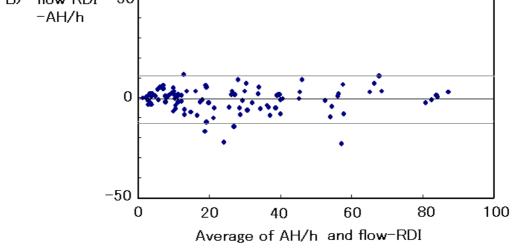


Fig. 4 The correlation between the apnea-hypopnea index (AHI) and oxygen desaturation index (ODI) was similar to that between the AHI and flow-RDI as a whole (r=0.94 vs. r=0.94). For the normal weight subjects (closed circle) the correlation between the AHI and ODI was poorer than between the AHI and flow-RDI (r=0.87 vs. r=0.93). For the over-weight subjects (open circle) the correlations were equivalent (r=0.94 vs. r=0.94).

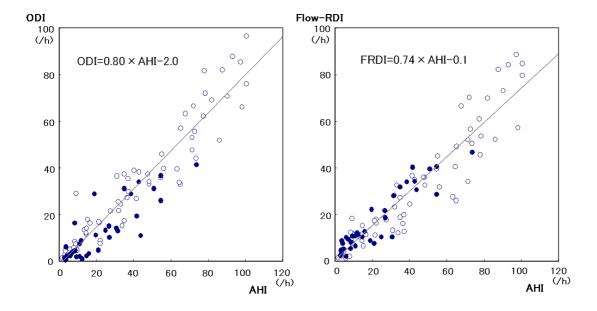


Fig. 5 Bland & Altman plots in subjects with AHI less than 30. (A) Difference between the oxygen desaturation index (ODI) and apnea-hypopnea index (AHI). (B) Difference between the flow-RDI and AHI.

