Usefulness of SD-101, a non-restrictive device developed for screening sleep apnea-hypopnea syndrome

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Usefulness of SD-101, a non-restrictive device developed for screening sleep apnea-hypopnea syndrome

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Summary at a Glance

The purpose of this study was to examine the clinical usefulness of the SD-101, a nonrestrictive, sheet-like

portable monitoring device using an array of 162 thin membrane-type pressure sensors developed in Japan for

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screening sleep apnea-hypopnea syndrome (SAHS). We measured sleep-disordered breathing in 201 subjects

attending our hospital with suspected SAHS (suspected SAHS group) and in all 165 male employees of a

transport company in Matsumoto city (screening group) using the SD-101 and polysomnography (PSG)

simultaneously. Significant correlations were seen between apnea-hypopnea index (AHI) for total recording time

on PSG and respiratory disturbance index (RDI) measured with the SD-101 in both the suspected SAHS group (r

= 0.88) and the screening group (r = 0.92). Receiver operating characteristic analysis revealed that sensitivity and

specificity for differentiating SAHS were 89.5% and 85.8%, respectively, when the cut-off value for RDI was

14.0 events/h. These findings suggest that the SD-101 is useful in screening for SAHS.

ABSTRACT

Background and objective: Kentzmedico in Japan has developed the SD-101 as a nonrestrictive, sheet-like medical device with an array of pressure sensors, to automatically detect sleep-disordered breathing (SDB) by sensing gravitational alterations in the body corresponding to respiratory movements. The purpose of this study was to examine the clinical usefulness of the SD-101 for screening sleep apnea-hypopnea syndrome (SAHS).

Methods: Nocturnal polysomnography (PSG) and SD-101 recordings were run simultaneously and compared for 201 subjects attending our hospital with suspected SAHS (suspected SAHS group) and in all 165 male employees of a transport company (screening group).

Results: PSG revealed apnea-hypopnea index (AHI) < 5, $5 \leq$ AHI < 15, $15 \leq$ AHI < 30, $30 \leq$ AHI < 60, and AHI ≥ 60 events/h in 39, 35, 38, 68 and 21 subjects in the suspected SAHS group and 103, 34, 12, 12 and 4 subjects in the screening group, respectively. Central SAHS and obstructive SAHS were subsequently diagnosed in 11 (5.5%) and 135 (67.2%) subjects in the suspected SAHS group and 5 (3.0%) and 39 (23.6%) subjects in the screening group, respectively. Significant correlations were apparent between AHI and respiratory disturbance index (RDI) measured with the SD-101 in both the suspected SAHS group (r = 0.88) and screening group (r = 0.92). Receiver operating characteristic analysis revealed 89.5% sensitivity and 85.8% specificity in identifying SAHS, using an RDI of 14.0 events/h.

Conclusion: These findings suggest that the SD-101 is a useful device for screening SAHS.

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Key words: sleep apnea syndrome (SAS); polysomnography (PSG); portable device; screening; pressure sensor

array.

Running Head: Portable device for screening SAS

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INTRODUCTION

Periodic hypoxemia and sleep disturbance resulting from repeated apnea and hypopnea while sleeping in patients with sleep apnea-hypopnea syndrome (SAHS) causes excessive daytime sleepiness (EDS), hypertension, impaired glucose tolerance, hyperlipidemia, liver dysfunction, and arteriosclerosis[1-4]. SAHS is also an important risk factor in the development of ischemic heart disease and cerebrovascular disease[5,6]. EDS resulting from SAHS has been suggested to cause traffic and occupational accidents and decrease productivity at work. Including associations with lifestyle-related diseases, SAHS is becoming an increasingly large social problem[7-9]. SAHS is not a rare disease at all, reportedly occurring in 4% of men and 2% of women ≥30 years old in the United States[10]. Morbidity in Asian populations is suggested to be even higher[11,12], although no reliable epidemiological surveillance has yet been performed in Japan. However, most patients with SAHS remain undiagnosed, as patients often do not become suspicious of the few symptoms they notice and do not attend medical institutions. Determining efficient screening methods for patients with potential SAHS is thus crucial to achieving correct diagnosis and timely treatment. Polysomnography (PSG) is the gold-standard examination for the diagnosis of SAHS, but requires the placement of numerous sensors on the body and is restrictive for subjects. Performing PSG for all subjects with suspected SAHS is difficult, given the expense and the need for hospitalization. The development of a simplified, high-performance portable screening device with which to conduct screening tests at home has thus been highly anticipated. Some simplified screening devices have now been developed and applied widely. However, the Portable Monitoring Task Force of the American Academy of Sleep Medicine (AASM)[13]

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recommended that unattended portable monitoring for the diagnosis of obstructive sleep apnea (OSA) should only

be performed in conjunction with a comprehensive sleep evaluation, and may be used as an alternative to PSG for

the diagnosis of OSA in patients with high pretest probability of moderate to severe OSA. The AASM also stated

that portable monitoring is inappropriate for general screening of asymptomatic populations, based on a review of

the literature and consensus. The lack of reliability in portable monitoring devices may be due to lower sensitivity

and specificity, particularly for mild to moderate SAHS, with risks of sensors attached to the body coming off or

not working, and the inability to judge waking or sleeping status as common problems for portable devices.

Higher-performance, nonrestrictive portable monitoring devices are now expected.

An apparatus to detect respiratory movements by sensing changes in body pressure has thus been developed,

using multipoint membrane-type pressure sensors on a sheet[14,15]. Kentzmedico in Japan applied this technology to

develop a nonrestrictive medical device, the SD-101, to detect sleep disordered breathing (SDB)[16,17]. The SD-101

is a sheet-like apparatus with several millimeters thick, containing 162 membrane-type pressure sensors to sense

gravitational alterations in the body accompanying respiratory movements, then converting these changes in

pressure distributions into breathing wave forms and automatically analyzing the resulting breathing patterns. A

good correlation coefficient has been demonstrated between apnea-hypopnea episodes on the PSG and SD-101 in

69 subjects with suspected SAHS (r=0.947), with little influence from body position (r=0.954 in supine position;

r=0.958 in lateral position)[16].

The purpose of the present study was not only to compare SDB as detected by SD-101 and PSG, but also to

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confirm the usefulness of SD-101 as a screening device for SDB in the general population. In previous studies,

correlations between respiratory disturbance index (RDI) obtained from portable devices and apnea-hypopnea

index (AHI) on PSG have been obtained from populations with suspected SAHS, thus showing a relatively high

rate of SDB and severe SDB. The correlation coefficient is naturally likely to be higher in such populations than

in a general population, where the rate of severe SDB is low. Higher ability to differentiate subjects showing mild

to moderate SDB from normal subjects may thus be needed for a screening device. Also, because the relationship

between traffic accidents due to EDS and SAHS has been attracting attention in the community, we recruited not

only subjects attending our hospital with suspected SAHS (suspected SAHS group), but also 165 employees

whose daily work mainly involved driving a truck for a transport company as a general population (screening

group). In both groups, SDB was measured using the SD-101 at the same time as PSG. Data obtained using the

SD-101 and PSG were analyzed and compared.

MATERIALS AND METHODS

Subjects

*Suspected SAHS group***:** Between March 2004 and August 2007, a total of 207 patients admitted to Shinshu

University Hospital based on concerns about SAHS or complaints of habitual snoring, EDS, or symptoms or

physical examination leading to suspected SAHS were recruited for the study, after removing potential subjects

meeting to the exclusion criteria. All subjects provided written informed consent prior to enrolment. Pregnant

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women or women who might become pregnant, patients with body weight <15 kg or >200 kg and patients who had been treated for SAHS or had undergone implantation of medical devices such as a cardiac pace maker were excluded from this study.

Screening group: We selected all employees of a transport company in Matsumoto city. Most of the employees were male and their work mainly involved driving a truck for long distances. A small number of women worked as office workers in the company, but did not provide written informed consent. As a result, all subjects who provided written informed consent and were enrolled in this study were male (n = 165). Characteristics of subjects from each group are shown in Table 1.

Protocol

Examination of the suspected SAHS group was performed at Shinshu University Hospital or Shironishi Hospital, while the screening group was examined in the accommodations of Asahi Hall in Shinshu University. The SD-101 was spread between the mattress and sheet, and installation of PSG was started at 20:00. An electrical signal was devised to be entered into a digital polygraph (Alice III; Chest, Tokyo, Japan) to synchronize the measurement of SD-101 and PSG. Simultaneous measurements by both the SD-101 and PSG began at 21:00 and finished at 06:00 the next morning. Analysis of data from the SD-101 was performed automatically using exclusive analytical software on a personal computer, and PSG analysis was performed in combination with the

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automatic analysis and the manual analysis. We compared the results of RDI measured using the SD-101 and AHI

for the total recording time (TRT) calculated from PSG. Analysis of PSG was performed by PSG technicians who

were trained under common criterion and were blinded to data from the SD-101. All study protocols were

approved by the Human Ethics Committee of Shinshu University School of Medicine and all subjects provided

written informed consent prior to enrolment.

SD-101

The SD-101 is a sheet-type apparatus 555 mm long, 1235 mm wide and 5 - 7 mm thick, weighing about 2.2 kg.

Within this device, 162 thin membrane-type pressure sensors with high sensitivity are arranged at 40-mm intervals

(Fig. 1). The device is spread between the mattress and a sheet for examinations. The multipoint sensors

automatically detect gravitational alterations in the body corresponding to respiratory movements. As a brief

explanation, the diaphragm shifts toward the abdomen and the lungs expand with air during inspiration. The

pressure distribution per unit area applied to sensors in contact with the chest and abdomen thus paradoxically

changes. These changes in pressure distribution are reversed during expiration. Respiratory movements can

therefore be detected as changes in pressure distributions. To detect respiratory movements more accurately and to

exclude noise due to body movements, this device automatically selects one sensor sensing changes in pressure

corresponding to the most marked respiratory movements from the 162 sensors as a basis sensor, and other

sensors sensing pressure alteration are divided into two groups. One group comprises sensors showing a phase

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difference from the basis sensor of around 0 (rad) and the other group comprises sensors showing a phase

difference from the basis sensor of around π [rad] ($0.75\pi < \tau < 1.25\pi$ [rad]). Pressures in each group are totaled

and differences between totals are calculated and converted to respiratory waveforms. This operation enables

appropriate analysis of respiratory movement in any body position in consideration of phase differences in

pressure alteration, reduces the influence of noise and can remove the influence of offsets due to phase differences

[14]. Furthermore, the device automatically detects body position by associating the area of body in contact with the

sheet and pressure distributions. Information from overnight (available for 10 h) is recorded into a memory card.

After examination, data recorded in the memory card are uploaded to a personal computer and automatically

analyzed using exclusive analytical software. The SD-101 automatically judges apnea and hypopnea as present

when the pressure change corresponding to respiratory movement decreases to <30% from mean baseline values

and continues for ≥10 s followed by a voluntary breathing pattern corresponding to hyperventilation. RDI was

defined as the average number of events per hour for apnea and hypopnea during the TRT. In a preliminary study,

the algorithms were frequently examined in a time-matched comparison with PSG data, and the decrease to <30%

in respiratory wave forms obtained from digital signals converted from analog signals of pressure changes was

equivalent to hypopnea defined as a significant reduction of ≥30% in oral and nasal airflow and respiratory effort

with a ≥3% decrease in oxyhemoglobin saturation for ≥10 s on PSG. Furthermore, the SD-101 can display all raw

data to allow manual scoring or editing of automated scoring by a technologist.

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Overnight full PSG

All full PSGs were performed using a digital polygraph (Alice III; Chest) with a clinical technologist in

attendance. Standard PSG montages were used as follows: C4-A2, C3-A1, O2-A1 and O1-A2

electroencephalography (EEG); left and right electrooculography (EOG); submental electromyography (EMG); a

nasal cannula to measure nasal pressure; a thermistor to monitor nasal and oral flow; movement sensors for left

and right tibialis anterior muscles; respiratory effort by thoracoabdominal inductive plethysmography;

electrocardiography (ECG); finger pulse oximetry; a neck microphone to record snoring; and a sensor on a

thoracic belt to evaluate body posture. Data were recorded overnight for 9 h from 21:00 to 06:00 the next morning.

Apnea was defined as the cessation of airflow for $\geq$10 s. Hypopnea was defined as a significant reduction of $\geq$30%

in oral and nasal airflow and respiratory effort with a decrease in oxyhemoglobin saturation (SpO_2) of $\geq$3% for

$\geq$10 s[18]. The average hourly frequency of apneic and hypopneic episodes was defined as the AHI. Central apnea

was that unaccompanied by evidence of respiratory effort. Obstructive apnea was that seen with evidence of

continuous respiratory effort. Mixed apnea began as central apnea but displayed respiratory effort with evidence

of obstructive apnea later in the apneic interval. OSA and central sleep apnea (CSA) were also classified

according to the dominance of each apnea type. Patients were considered to display SAHS, if the AHI for total

sleeping time (TST) was $\geq$15 events/h with or without subjective symptoms, *e.g.*, EDS or AHI $\geq$5 and <15

events/h with subjective symptoms in accordance with the criteria of the International Classification of Sleep

Disorders 2[19].

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Statistics

Values shown in the text, figures and tables are presented as mean ± standard deviation (SD). Simple correlations between variables in the suspected SAHS group and screening group were examined by calculating Pearson's product correlation coefficient. Cut-off values of RDI measured using the SD-101 to differentiate AHI for TST ≥5 events/h from normal, AHI ≥15 events/h and clinically diagnosed SAHS were calculated from ROC analysis, with sensitivity and specificity determined in each case. All statistical analyses except Bland-Altman analysis (MedCalc version 10.2; MedCalc Software, Mariakerke, Belgium) were performed using Windows-compatible software (Stat Flex version 5.0; Artech, Osaka, Japan). Values of $P < 0.05$ were considered statistically significant for all analyses.

RESULTS

Final diagnosis on PSG

Suspected SAHS group: Six subjects were excluded from analysis in this study because TST ≥6 h could not be obtained. A final total of 201 subjects ranging in age from 12 to 86 years old were analyzed. Final diagnoses of these subjects were as follows: normal, n = 39 (AHI for TST <5 events/h); and sleep-related breathing disorder (SRBD), n = 162 (80.6%). Mean AHI was 28.6 ± 23.0 events/h. Severity of SRBD was as follows: mild, n = 35 (5 ≤ AHI < 15 events/h); moderate, n = 38 (15 ≤ AHI < 30 events/h); severe, n = 68 (30 ≤ AHI < 60 events/h); and

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very severe, n = 21 (AHI ≥ 60 events/h). When we followed the criteria of the International Classification of Sleep

Disorders 2[19], 11 subjects were diagnosed with central SAHS (CSAHS) (5.5%) and 135 subjects were diagnosed

with obstructive SAHS (OSAHS) (67.2%). No subjects displayed a Cheyne-Stokes respiratory (CSR) pattern.

Screening Group: All 165 subjects aged 18 to 69 years old were able to complete PSG and slept for >6 h. Final

diagnoses for these subjects were as follows: normal, n = 103 (AHI < 5 events/h for TST); and SRBD, n = 62

(37.6%). Mean AHI was 8.9 ± 14.3 events/h. Severity of SRBD was as follows: mild, n = 34; moderate, n = 12;

severe, n = 12; and very severe, n = 4. When we followed the criteria of the International Classification of Sleep

Disorders 2, OSAHS was diagnosed in 39 subjects (23.6%) and CSAHS was diagnosed in 5 subjects (3.0%).

Again, no subjects displayed a CSR pattern.

Relationship between RDI measured with SD-101 and AHI on PSG in suspected SAHS and screening groups

Suspected SAHS group: We compared RDI for TRT measured using the SD-101 and AHI for TRT obtained from

PSG measured with Alice III, as the SD-101 cannot detect whether the subject in sleeping. We observed an

extremely close correlation between RDI and AHI for TRT obtained from PSG (r = 0.88) (Fig. 2, left). With the

SD-101, sensitivity and specificity for detecting AHI ≥5 events/h for TRT on PSG were 100% and 32.5%,

respectively, for detecting AHI ≥15 events/h for TRT were 96.6% and 60.0%, respectively, and for detecting AHI

≥30 events/h for TRT were 81.0% and 80.0%, respectively (Fig. 3, left).

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*Screening group***:** A very close correlation was observed between RDI measured with the SD-101 and AHI for

TRT obtained from PSG (r = 0.92) (Fig. 2, right). With the SD-101, sensitivity and specificity for detecting AHI

≥5 events/h for TRT on PSG were 100% and 41.3%, respectively, for detecting AHI ≥15 events/h for TRT were

100% and 90.1%, respectively, and for detecting AHI ≥30 events/h for TRT were 92.0% and 98.0%, respectively

(Fig. 3, right).

Bland-Altman plot analysis was performed to allow for comparison between the two measurements using sum

data (n = 366) in both suspected SAHS and screening groups (Fig. 4). Mean difference in AHI obtained from PSG

and RDI measured using the SD-101 was -4.7 ± 7.7 events/h. To evaluate the clinical utility of the SD-101 as a

screening device for SAHS, we performed ROC analysis. Cut-off values of RDI measured with the SD-101 to

differentiate AHI ≥5 events/h for TST from normal, AHI ≥15 events/h for TST and clinically diagnosed SAHS

were calculated from ROC analysis using the sum data (n = 366). The area under the curve (AUC) in ROC

analysis to differentiate AHI ≥5 events/h for TST, AHI ≥15 events/h for TST and clinically diagnosed SAHS from

normal was 0.96, 0.97, and 0.95, respectively. Sensitivity and specificity to differentiate AHI ≥5 events/h for TST

were 87.5% and 88.0%, respectively, when the cut-off value for RDI was 12.4 events/h. Sensitivity and specificity

to differentiate AHI ≥15 events/h for TST were 89.7% and 90.5%, respectively, when the cut-off value for RDI

was 18.6 events/h. Sensitivity and specificity to differentiate SAHS were 89.5% and 85.8%, respectively, when

the cut-off value for RDI was 14.0 events/h.

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DISCUSSION

The AASM classifies inspection devices used for the evaluation of SAHS into four levels in terms of measurement items[20]. Full PSG under monitoring by a skilled laboratory technician forms level 1 investigation, for which accuracy is considered the highest, representing the gold standard for the diagnosis of SAHS. Next, the same measurements without monitoring by a laboratory technician and with online paper and monitor form level 2, measurement of cardiorespiratory items without sleep parameters is level 3, and measurement of one or two items is classified as level 4, which has been recognized as unable to diagnose SDB accurately. Time-matched comparisons between RDI measured by portable devices without EEG and AHI measured by PSG reportedly show a good correlation coefficient of 0.7 - 0.94[21-25]. Previous portable level 4 devices have not shown good correlations with PSG data, and sensitivity and specificity have not been particularly high[21-23]. However, newly developed portable level 4 devices have shown higher correlation coefficients with PSG and increased accuracy[24,26]. SD-101 corresponds to a level 4 measurement device, but the time-matched comparison with RDI measured by SD-101 and AHI calculated from PSG showed a very close correlation, with correlation coefficients of 0.88 in the suspected SAHS group and 0.92 in the screening group in this study as well as the newly developed portable level 4 devices. In previous studies, correlations between RDI obtained from portable devices and AHI on PSG have been obtained from the suspected SAHS population, thus showing relatively high rates of SDB, especially for severe SDB. However, in this study, high correlation coefficients were observed even in a general adult population consisting of numerous normal subjects showing AHI <5 events/h (62.4%). However, the

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specificity for differentiating mild SDB from normal was comparatively low in both suspected SAHS and screening groups. The SD-101 may overestimate RDI by incorrectly recognizing some body movements as SDB. However, when the cut-off value for RDI was changed to 12.4 events/h based on ROC analysis, sensitivity and specificity to differentiate AHI $\geq$5 events/h were 87.5% and 88%, respectively, representing an improved specificity. The SD-101 can thus be considered as a useful device for screening of SAHS when the cut-off value for RDI is fixed at 12.4 events/h.

Portable level 3 devices show higher sensitivity and specificity than level 4 devices, and are thus recognized as the most reliable portable devices[27,28]. However, sensors must be installed on the body as well as with older level 4 devices. When the installation is loose, events cannot be sensed by auto-analysis and analysis may become difficult even with manual analysis. Moreover, sensors might be dislodged when the subject moves during sleep. In the case of level 4 portable devices, these sensor troubles may represent an important problem. The SD-101 is a nonrestrictive, noninvasive portable device that can be folded to compact size to easily take home. SDB can be measured simply by spreading the sheet-like device between the mattress and sheet, allowing detection of SDB during natural sleep without restraining the subject by connections to a device. Also, no measurement problems such as sensor dislodgement are encountered and there is no large influence of body position. Furthermore, this portable device can display all raw data to allow manual scoring or editing of automated scoring by a technician. The usefulness of the SD-101 thus seems superior to existing portable devices for detecting SAHS, and the cost of the SD-101 is about one-tenth that of a PSG system. This is thought to be a definite advantage for a screening

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device.

However, the SD-101 is not perfect, and some problems and limitations must be discussed. The specificity of SD-101 to differentiate mild SDB from normal was relatively low, possibly due to the incorrect detection of some body movements as SDB, and development of a high-quality filter to exclude the effects of body movement may be necessary. The SD-101 can only detect respiratory events, not desaturation. The SD-101 may thus underestimate hypopnea in subjects with lung disease or obesity who show marked desaturation during hypopnea, because hypopnea is defined not only as a respiratory event, but also as a degree of desaturation. A new version of the SD-101 including an SpO_2 monitor is therefore under development. Furthermore, the inability to judge waking or sleeping status may contribute to lower RDI compared with AHI for TST, and this has been a common problem for portable devices.

Young et al.[10] reported that 602 subjects aged 30 to 60 years selected at random from 3513 employees in Wisconsin in the United States were studied by overnight PSG to determine AHI. This study revealed the prevalence of SDB was 9% for women and 24% for men when defined as AHI $\geq$5 events/h, and 4% for women and 9.1% for men when defined as AHI $\geq$15 events/h. In addition, 2% of women and 4% of men met the diagnostic criteria for SAHS, as AHI $\geq$5 events/h with daytime hypersomnolence, and these results are now quoted worldwide for the prevalence of SAHS. In Japan, Kato et al.[11] reported the prevalence of SDB as measured by nocturnal pulse oximetry among 249 male workers aged 20 to 65 years as 18.1% when SDB was defined as 3% oxygen desaturation index (ODI) $\geq$15 events/h. Nakayama-Ashida et al.[12] have also conducted a

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cross-sectional survey using a self-administered questionnaire and unattended home cardiorespiratory sleep studies (level 3) with actigraphy for two nights to diagnose SDB among 322 male employees aged 23 to 59 years in Osaka, Japan. They reported prevalences of mild ($5 \leq$ RDI < 15 events/h), moderate ($15 \leq$ RDI < 30 events/h), and severe (RDI ≥ 30 events/h) SDB in this population of 37.4%, 15.7%, and 6.6%, respectively. The prevalence of OSAHS (RDI ≥ 5 events/h and Epworth sleepiness scale score >10) was 17.6%. The present study revealed that prevalences of mild SDB, moderate SDB, severe SDB, and OSAHS according to the criteria of the International Classification of Sleep Disorders 2 in a male working population aged 18 to 69 years as detected by full PSG (level 1) regardless of subjective symptoms were 20.6%, 7.3%, 9.7% and 23.6%, respectively. This is thus the first report on the prevalences of SDB and OSAS in a male working population in Japan detected using level 1 full PSG. The prevalence of SDB was lower and the prevalence of OSAHS was higher than previously reported by Nakayama-Ashida et al.[12], and these differences may be attributable to differences between portable devices and full PSG and differences in the criteria for SAHS. In any case, prevalences of SDB and SAHS in the Japanese adult male population are suggested to be higher than those in the United States.

OSAHS patients reportedly display twice the risk of hypertension, three times the risk of cardiovascular disease, four times the risk of cerebrovascular disease, and 1.5 times the risk of diabetes mellitus compared with individuals without SAHS. The survival rate for patients with severe OSAHS after 9 years is about 63% when restricted to severe SAS patients without treatment, with the remaining 37% dying of myocardial infarction or cerebrovascular disease[29]. An observational study to compare incidences of fatal and non-fatal cardiovascular

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events in simple snorers, patients with untreated and treated OSAHS with continuous positive airway pressure (CPAP), and healthy men recruited from the general population yielded rather shocking results[6]. Multivariate analysis, adjusted for potential confounders, showed that untreated severe OSAHS significantly increased the risk of fatal and non-fatal cardiovascular events compared with healthy participants whereas the risk of fatal and non-fatal cardiovascular events in OSAHS patients treated with CPAP was the same as in healthy participants. These findings suggest that CPAP treatment for severe OSAHS can reduce the mortality rate due to cardiovascular events. An estimated 2 million OSAHS patients reside in Japan, whereas only 20,000 people receive CPAP treatment, and many patients remain to be diagnosed and treated[30]. The SD-101, a new nonrestrictive portable SDB monitoring device, appears to offer relatively high performance with high sensitivity and specificity for detecting SDB and may contribute to screening SAHS, and appropriate diagnosis and treatment with CPAP can reduce the mortality of OSAHS.

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Table 1. Characteristics of subjects in the suspected sleep apnea-hypopnea syndrome (SAHS) group and

screening group

	Suspected SAHS group	Screening group
n	201	165
Sex, male/female	155/46	165/0
Age, years	53.8 ± 15.7	43.2 ± 11.6
Height, cm	165.4 ± 8.8	169.6 ± 6.0
Weight, kg	73.4 ± 19.9	68.1 ± 11.0
BMI, kg/m^2 (range)	26.6 ± 5.7 (16.6 - 51.0)	23.6 ± 3.3 (16.8 - 37.1)
ESS	6.8 ± 4.8	4.6 ± 3.7
TIB, min	530 ± 72	623 ± 87
TST, min	422 ± 93	485 ± 104
WK, min	104 ± 75	132 ± 77
Stage 1, min	101 ± 69	97 ± 51
Stage 2, min	250 ± 87	299 ± 82
Stage 3, min	13 ± 19	7 ± 14
Stage 4, min	2 ± 8	1 ± 3
REM sleep, min	60 ± 31	82 ± 35

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AHI, events/h	28.6 ± 23.0	8.9 ± 14.3
CAI, events/h	2.1 ± 4.2	0.4 ± 0.7
OAI, events/h	14.5 ± 18.8	3.9 ± 9.4
MAI, events/h	3.2 ± 6.5	0.2 ± 0.8
Hypopnea, events/h	9.7 ± 9.5	4.1 ± 6.3
Arousal index, events/h	23.8 ± 18.0	15.7 ± 11.5
$SpO_2 < 90\%$ (% TIB)	10.3 ± 13.9	2.3 ± 7.4
Minimum SpO_2, %	71.8 ± 15.1	86.4 ± 5.8
3% desaturation (TIB), episodes/h	26.6 ± 27.0	8.6 ± 12.6

Values represent mean ± SD. BMI, body mass index; ESS, Epworth sleepiness scale; TIB, total in bed; TST, total

sleep time; WT, waking time; REM, rapid eye movement; AHI, apnea-hypopnea index; CAI, central apnea index;

OAI, obstructive apnea index; MAI, mixed apnea index.

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FIGURE LEGENDS

Figure 1: The SD-101 is a sheet-type device with an array of 162 thin, membrane-type pressure sensors at equal

intervals of 40 mm to detect gravitational alterations in the body corresponding to respiratory movements.

Supine/prone and lateral body positions can also be detected. Information from overnight is recorded into a

memory card and automatically analyzed by analytical software.

Figure 2: Correlation between respiratory disturbance index (RDI) measured automatically with the SD-101 and

apnea-hypopnea index (AHI) for total recording time (TRT) calculated from PSG in the suspected sleep

apnea-hypopnea syndrome (SAHS) group (n = 201, left side) and in the screening group (n = 165, right side).

Figure 3: Relationship between severity of sleep disordered breathing measured automatically with the SD-101

and apnea-hypopnea index (AHI) for total recording time (TRT) calculated from PSG in the suspected sleep

apnea-hypopnea syndrome (SAHS) group (n = 201, left side) and in the screening group (n = 165, right side).

Figure 4: Bland-Altman plot of differences in AHI obtained from PSG and RDI measured using the SD-101 (n =

366). Solid lines represent mean differences, and dashed lines represent 1.96 SDs of the difference from the mean.

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The SD-101 is a sheet-type device with an array of 162 thin, membrane-type pressure sensors at equal intervals of 40 mm to detect gravitational alterations in the body corresponding to respiratory movements. Supine/prone and lateral body positions can also be detected. Information from overnight is recorded into a memory card and automatically analyzed by analytical software.
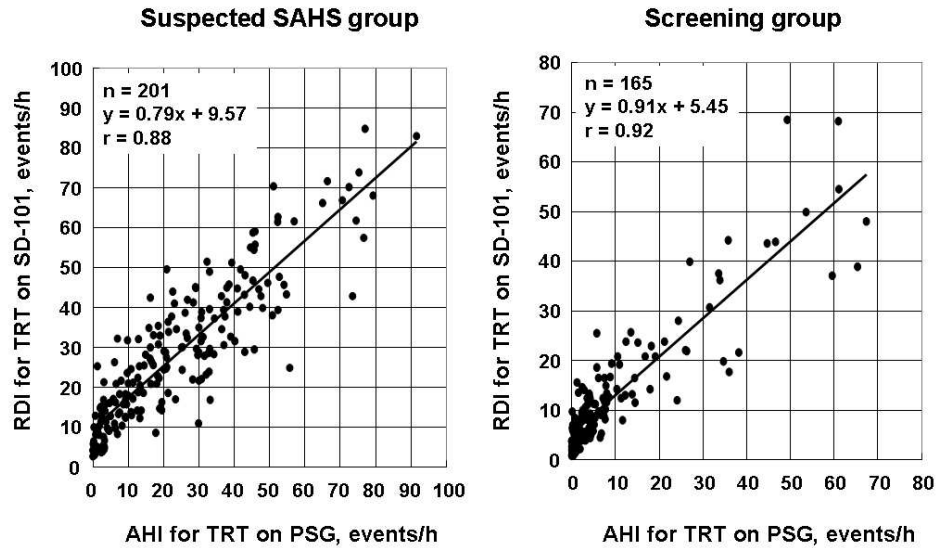285x190mm (96 x 96 DPI)

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Suspected SAHS group

n = 201
y = 0.79x + 9.57
r = 0.88

RDI for TRT on SD-101, events/h

AHI for TRT on PSG, events/h

Screening group

n = 165
y = 0.91x + 5.45
r = 0.92

RDI for TRT on SD-101, events/h

AHI for TRT on PSG, events/h

Correlation between respiratory disturbance index (RDI) measured automatically with the SD-101 and apnea-hypopnea index (AHI) for total recording time (TRT) calculated from PSG in the suspected sleep apnea-hypopnea syndrome (SAHS) group (n = 201, left side) and in the screening group (n = 165, right side).
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A. Suspected SAHS group

RDI for TRT on SD-101, events/h

RDI \ AHI	0~5	5~15	15~30	30~60	60~
60~	0	0	0	4	9
30~60	0	3	23	41	2
15~30	6	25	20	19	0
5~15	23	14	4	0	0
0~5	14	0	0	0	0

AHI for TRT on PSG, events/h

B. Screening group

RDI for TRT on SD-101, events/h

RDI \ AHI	0~5	5~15	15~30	30~60	60~
60~	0	0	0	2	0
30~60	0	0	3	8	1
15~30	1	12	9	1	0
5~15	63	20	0	0	0
0~5	45	0	0	0	0

AHI for TRT on PSG, events/h

Relationship between severity of sleep disordered breathing measured automatically with the SD-101 and apnea-hypopnea index (AHI) for total recording time (TRT) calculated from PSG in the suspected sleep apnea-hypopnea syndrome (SAHS) group (n = 201, left side) and in the screening group (n = 165, right side).
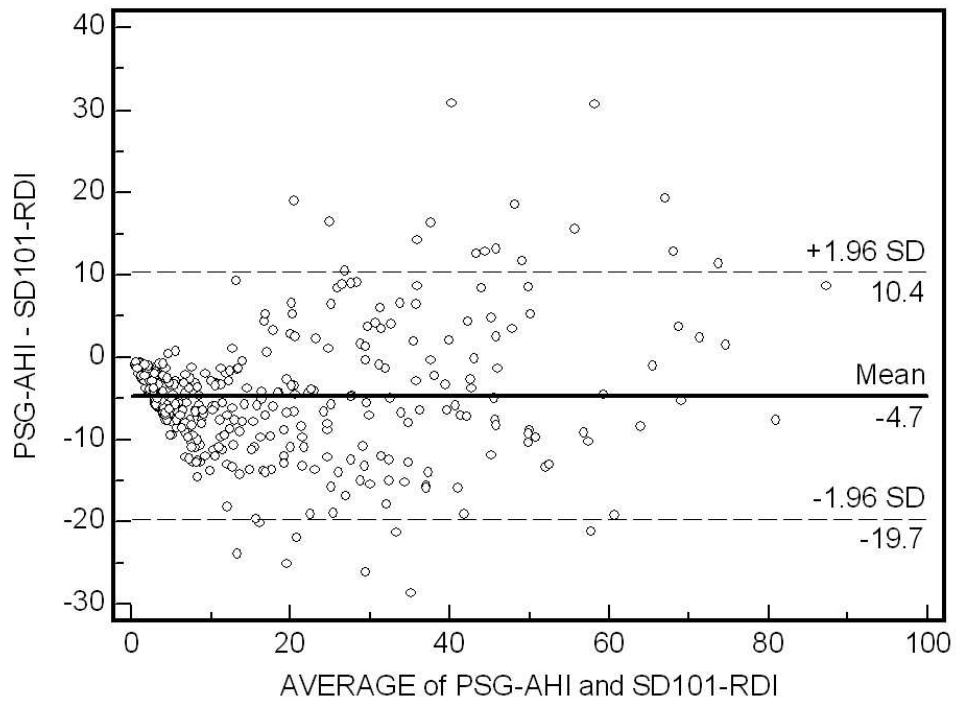285x190mm (96 x 96 DPI)

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Bland-Altman plot of differences in AHI obtained from PSG and RDI measured using the SD-101 (n = 366). Solid lines represent mean differences, and dashed lines represent 1.96 SDs of the difference from the mean.
254x190mm (96 x 96 DPI)