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SCIENTIFIC INVESTIGATIONS

Validation of a New System Using Tracheal Body Sound and Movement Data for Automated Apnea-Hypopnea Index Estimation

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Study Objectives: The current gold standard for assessment of obstructive sleep apnea is the in-laboratory polysomnography. This approach has high costs and inconveniences the patient, whereas alternative ambulatory systems are limited by reduced diagnostic abilities (type 4 monitors, 1 or 2 channels) or extensive setup (type 3 monitors, at least 4 channels). The current study therefore aims to validate a simplified automated type 4 monitoring system using tracheal body sound and movement data.

Methods: Data from 60 subjects were recorded at the University Hospital Ulm. All subjects have been regular patients referred to the sleep center with suspicion of sleep-related breathing disorders. Four recordings were excluded because of faulty data. The study was of prospective design. Subjects underwent a full-night screening using diagnostic in-laboratory polysomnography and the new monitoring system concurrently. The apnea-hypopnea index (AHI) was scored blindly by a medical technician using in-laboratory polysomnography (AHI_{PSG}). A unique algorithm was developed to estimate the apnea-hypopnea index (AHI_{est}) using the new sleep monitor.

Results: AHI_{est} strongly correlates with AHI_{PSG} (r^2 = .9871). A mean ± 1.96 standard deviation difference between AHI_{est} and AHI_{PSG} of 1.2 ± 5.14 was achieved. In terms of classifying subjects into groups of mild, moderate, and severe sleep apnea, the evaluated new sleep monitor shows a strong correlation with the results obtained by polysomnography (Cohen kappa > 0.81). These results outperform previously introduced similar approaches.

Conclusions: The proposed sleep monitor accurately estimates AHI and diagnoses sleep apnea and its severity. This minimalistic approach may address the need for a simple yet reliable diagnosis of sleep apnea in an ambulatory setting.

Clinical Trial Registration: Trial name: Validation of a new method for ambulant diagnosis of sleep related breathing disorders using body sound; URL: https://drks-neu.uniklinik-freiburg.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00011195; Identifier: DRKS00011195

Keywords: monitoring, movement analysis, respiratory sounds, sleep apnea

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INTRODUCTION

With a prevalence of 4% in adult men and 2% in women, obstructive sleep apnea (OSA) is one of the most common sleep-related breathing disorders.[1] Additionally, more than 75% of people suffering from moderate OSA are either undiagnosed or untreated.[2] OSA is characterized by multiple breathing cessations during the night due to different possible causes. If untreated, this disorder can lead to extensive daytime sleepiness[3] and an elevated risk for cardiovascular disease.[4–6] The main criteria used to indicate the severity of OSA is the apnea-hypopnea index (AHI), which describes the mean number of breathing pauses longer than 10 seconds per hour of sleep. Breathing pauses are divided into the categories apnea or hypopnea. Apneas are defined by at least 90% reduction in air flow and hypopneas are defined by at least 30% reduction in air flow including an event-related arousal and/or more than 3% oxygen desaturation.[7]

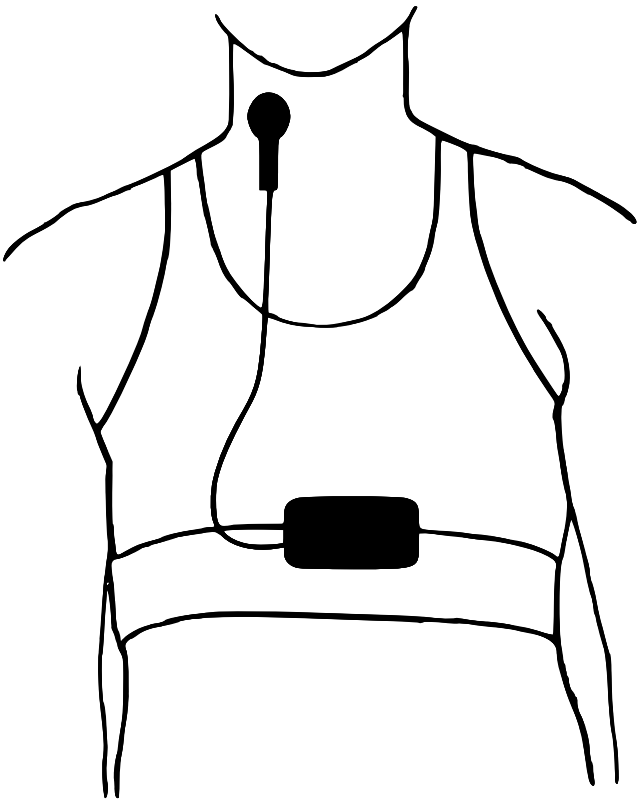
The current gold standard for the assessment of OSA is the in-laboratory polysomnography (PSG). This method requires an overnight stay of the patient in a sleep laboratory to record and evaluate multiple physiological signals by trained technicians. However, this approach is accompanied by high costs and inconveniences for the patient. Furthermore, the extensive recording equipment may considerably influence the sleep quality and thus falsify the subsequent diagnosis. Additionally, the time and labor intensive nature of the PSG paired with the

BRIEF SUMMARY

Current Knowledge/Study Rationale: Obstructive sleep apnea is one of the most common sleep-related breathing disorders. The current gold standard for assessment of obstructive sleep apnea is the in-laboratory polysomnography. This approach has high costs and inconveniences the patient, whereas alternative ambulatory systems are limited by reduced diagnostic abilities and complicated setup.

Study Impact: The presented new sleep monitor utilizes tracheal body sound and movement data to accurately diagnose the presence and severity of sleep apnea. This allows simple setup and high comfort, reducing the effect on sleep quality in comparison with in-laboratory polysomnography while outperforming existing ambulatory diagnostic systems and previously introduced similar approaches.

Figure 1—Abstract representation of the setup of the new sleep monitor system.



The microphone is attached to the neck while the remaining hardware is attached to the existing thoracic belt of the respiratory inductance plethysmograph during polysomnography.

increasing prevalence of OSA has led to a strong demand for appropriate hospital facilities. Therefore, several less extensive but similarly reliable methods have been developed. For the diagnosis of OSA these are mostly focused on ambulatory and screening applications and use either nasal airflow or peripheral oxygen saturation (SpO_2) or a combination of both for the diagnosis of OSA.[8,9] However, these signals induce several problems and limitations. Mouth breathing or misplacement causes nasal airflow to frequently fail to measure breathing. Additionally, relying exclusively on SpO_2 provides an insufficient specificity and sensitivity.[10] To overcome those limitations, multiple systems have been proposed that instead use breathing sounds as a main signal for the diagnosis of OSA. Here, breathing sounds are recorded either by ambient air microphones located in the vicinity of the patient[11,12] or by deploying special body sound microphones placed on the patient's neck. First studies with these systems revealed a strong correlation in AHI values with PSG.[13,14]

A new monitoring system for the diagnosis of OSA using body sounds and movement data was developed previously but has not yet been fully validated. The new monitoring system includes a unique algorithm to automatically detect apnea and hypopnea events and estimate apnea-hypopnea index (AHI_{est}). The new system is designed to be as comfortable and simple as possible in order to minimize its effect on sleep quality and allow its use at home without medical supervision. The current study aims to validate the new monitoring system in subjects with suspected OSA using the apnea-hypopnea index determined by PSG (AHI_{PSG}).

METHODS

Subjects

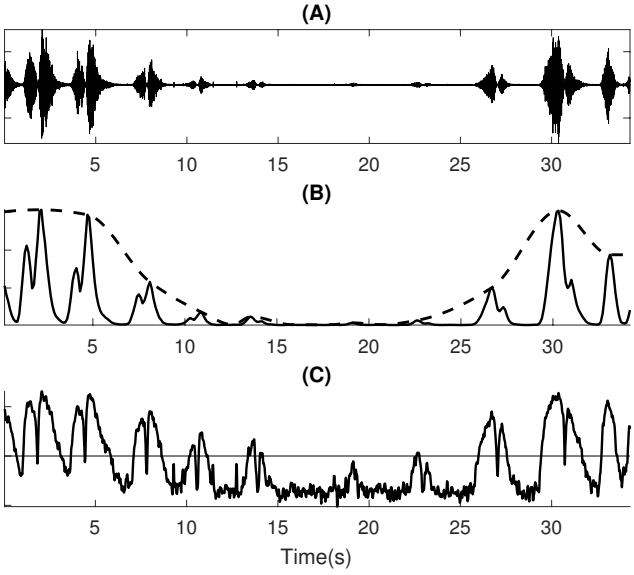
Data from 60 subjects were recorded at the sleep center of the University Hospital Ulm. Inclusion criteria included a suspicion of sleep-related breathing disorders diagnosed by a primary care physician and age between 18 and 90 years. Exclusion criteria included known allergies or intolerances with adhesive patches, serious illnesses, or diseases that affect the participation of the subjects in the study. During their stay subjects underwent a full-night screening using diagnostic PSG and the new monitoring system simultaneously. The study was approved by the ethics committee of the University of Ulm and all subjects gave written informed consent. In total, 4 recordings were excluded because of faulty body sound (n = 1), faulty airflow (n = 2) or faulty thoracic and abdominal respiratory (n = 1) recordings. Patients suffering from central sleep apnea or mixed forms (n = 4) and patients suffering from Cheyne-Stokes respiration (n = 2) were also excluded. Of the remaining 50 recordings, 13 patients suffered from mild, 11 from moderate, and 15 from severe OSA. OSA was not diagnosed in the remaining 11 patients.

Data Acquisition

PSG and the new monitoring system were set up by trained medical staff and monitored during the recording. Both recordings were performed concurrently. Recording started between 9:00 PM and 11:00 PM and ended between 5:00 AM and 7:00 AM. PSG was carried out by using the PSG system SOMNOlab (Co. Weinmann Geräte für Medizin GmbH + Co. KG, Kronsaalsweg 40, 22525 Hamburg, Germany). Electroencephalography was carried out including channels C3-A2 and C4-A1 with a sampling rate of 256 Hz. Furthermore, submental electromyography, unilateral anterior tibial electromyography, and bilateral electrooculography was included and sampled with 256 Hz. The oronasal airflow was recorded by using a thermistor and was sampled with 32 Hz. Additionally, the thoracic and abdominal respiratory movements were measured by using respiratory inductance plethysmograph and were sampled with 32 Hz. Oxygen saturation was recorded by using finger pulse oximetry and sampled with 16 Hz. Finally, a basic heart rate monitoring using a 1-lead electrocardiograph sampled with 256 Hz was also included.

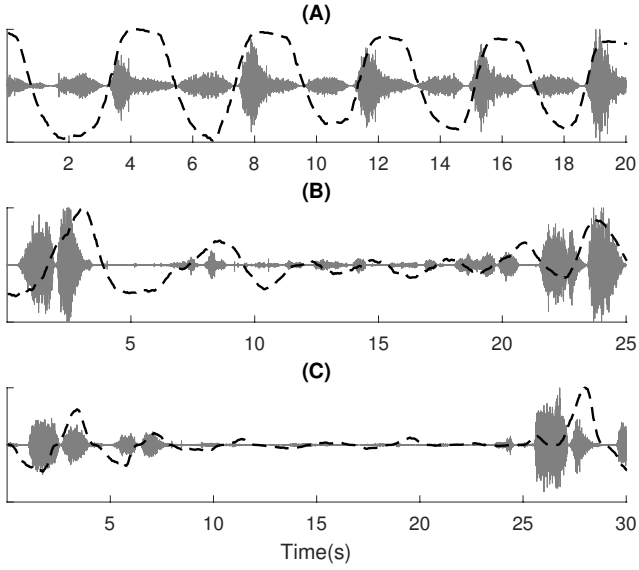
The new monitoring system was developed based on the preliminary system previously described by Kalkbrenner et al.[15] **Figure 1** shows an abstract representation of the setup. Tracheal body sound was recorded by a body sound microphone attached to the neck and sampled with 5 kHz. This commercially available microphone was designed for long-term monitoring of lung sounds to diagnose breathing disorders such as asthma and is part of a system called LEOSound (Co. Heinen+Löwenstein GmbH & Co. KG Arzbacher Straße 80,

Figure 2—Illustration of the keys steps of the developed algorithm using a typical apnea phase.



(A) Audio signal after preprocessing; **(B)** smooth envelope representing breathing cycles, the dashed curve represents local maxima of breathing cycles to detect drops in breathing amplitude; and **(C)** estimation of airflow. Everything below the horizontal line is considered no breathing.

Figure 3—Illustration of the relationship between oronasal airflow recorded by thermistor and tracheal body sound.



From top to bottom, the graphs show typical segments of **(A)** normal breathing, **(B)** hypopnea and **(C)** apnea. Dashed curve = thermistor, gray curve = tracheal body sound.

56130 Bad Ems, Germany). Actigraphy was carried out using an inertial measurement unit (IMU) housed together with the remaining recording hardware and attached to the existing thoracic belt of the respiratory inductance plethysmograph. The signals from accelerometer and gyroscope in the IMU were sampled with a rate of 250 Hz. The acquired data (sound and movements) was transmitted wirelessly to a laptop for storage and subsequent data analysis.

For apnea-hypopnea index calculation, apneas and hypopneas were scored according to American Academy of Sleep Medicine standards,[7] which define apneas by ≥ 90% drop of baseline flow amplitude with a duration of at least 10 seconds. Hypopneas are defined by ≥ 30% drop of baseline flow amplitude with a duration of at least 10 seconds including an event related arousal and/or ≥ 3% oxygen desaturation. At least 90% of the apnea or hypopnea duration must meet their correspondent amplitude reduction criteria. After data recording, a trained medical technician manually reviewed all 50 datasets. Apneas and hypopneas were scored solely using PSG data. The technician was blinded to the results of the new monitoring system. Finally, the AHI_{PSG} was calculated as the number of apneas and hypopneas per hour of sleep.

Analysis of Sound and Movement Data

In order to automatically calculate AHI_{est} by using the new monitoring system a unique algorithm was developed. The following details will give a summary of the proposed method.

To facilitate understanding, the key steps of the algorithm are exemplified in **Figure 2**. Initially the raw audio signal is filtered to obtain a preferably pure breathing sound signal by removing all disruptive and nonrelevant sounds (ie, background noise and heart sounds). By calculating the mean intensity of the preprocessed audio signal within short-term windows, every breathing cycle can be represented by a smooth time series. Interpolating the local maxima of single respiratory cycle to an envelope curve, long-term changes in breathing can be captured. If segments of this signal underlie an adaptive threshold for a certain time, they are identified as drops in breathing amplitude. Using this method allows capture of a broad spectrum of potential apnea and hypopnea segments. The following final step of the algorithm aims to classify these segments of amplitude drop in apnea, hypopnea, and normal breathing. **Figure 3** illustrates an example of such sequences in respiratory periods showing several signals and their relationship between the oronasal airflow (PSG) and the tracheal body sound (new sleep monitor). To apply the conventional definition of apneas and hypopneas, a value representing the normal airflow has to be calculated only by using the audio signal. The importance of this step is emphasized by the fact that during the night the overall relationship between breathing sound amplitude and airflow can vary significantly, mainly dependent on sleeping position. Based on the findings of previous studies[16–18] it is possible to continuously relate and revise certain features of every breathing cycle to the respective amount of airflow. Finally, this technique is utilized for the classification of the previously detected segments during the first step into apnea, hypopnea, or normal breathing.

In addition, the recorded movement data is used to improve the reliability of the detection algorithm by making it more robust against artefacts. Most audio artefacts within the recorded tracheal sound are caused by movements of the subject during sleep. These artefacts can easily be recognized by monitoring

Table 1—Anthropometric information of the study subjects (n = 50).

	Male	Female		
Sex, n	31	19		
	Mean	**Median**	**SD**	**IQR**
Age, years	57.42	58.00	14.24	20.75
BMI, kg/m²	31.27	31.18	6.58	8.90
AHI, events/h	21.38	16.29	18.69	30.76
ET, hours:minutes	07:14	07:14	00:35	00:47
TST, hours:minutes	05:03	05:22	01:19	02:09
WASO, hours:minutes	01:48	01:20	01:08	01:30
Number of awakening events	33.20	30.50	14.58	13.25
Sleep efficiency, %	69.89	76.00	17.08	22.48
S1, %	18.01	15.90	16.27	12.73
S2, %	55.41	57.15	16.49	17.63
S3, %	7.85	6.55	7.17	11.70
REM, %	18.72	15.60	11.19	10.90
ODI, events/h	19.03	12.05	19.29	29.78
T90, hours:minutes	00:33	00:09	00:59	00:40

AHI = apnea-hypopnea index, BMI = body mass index, ET = evaluation time (contains only artefact-free periods, only this time is considered for calculation of characteristic values), IQR = interquartile range, ODI = oxygen desaturation index (number of desaturation events per hour), SD = standard deviation, T90 = time while SpO_2 < 90%, TST = total sleep time, WASO = wake after sleep onset.

the movements of the subject. Additionally, most changes of amplitude in breathing sounds are caused by changes in the subjects' sleeping position due to acoustic coupling, which facilitates their detection by incorporating the provided movement data. Finally, the AHI_{est} is calculated as the number of detected apnea and hypopnea segments per hour, considering only artefact-free periods.

Statistics

MATLAB R-2015b (The MathWorks Inc., Natick, Massachusetts, United States) was used to perform all statistical analysis. An equivalence test for paired data was used to evaluate the agreement between AHI_{est} and AHI_{PSG}. The equivalence limits were set to a mean ± 5 AHI at a significance level of .05. To further prove diagnostic agreement between AHI_{est} and AHI_{PSG}, Bland-Altman and correlation analysis were carried out. Additionally, the performance of the presented new monitoring system was evaluated in detail by calculating the number of correctly and incorrectly classified apneas and hypopneas with regard to PSG. For subject classification into categories of mild, moderate, and severe OSA, thresholds defined by an American Academy of Sleep Medicine Task Force[19] were used (mild: AHI = 5–14, moderate: AHI = 15–30, severe: AHI > 30). Sensitivity, specificity, positive predictive and negative predictive value, and the unweighted Cohen kappa coefficient[20] were calculated accordingly. Receiver operating characteristic curves and the corresponding areas under the curves were calculated to evaluate the performance against the PSG results.

Table 2—System performance of the new monitoring system (n = 50).

	Sens.	Spec.	PPV	NPV	Cohen kappa (CI)
AHI ≥ 5	0.9091	0.9487	0.8333	0.9737	0.83 (0.65–1.02)
AHI ≥ 15	1.0000	1.0000	1.0000	1.0000	1.00 (1.00–1.00)
AHI ≥ 30	1.0000	0.9333	0.9722	1.0000	0.95 (0.86–1.05)

AHI = apnea-hypopnea index, CI = confidence interval, NPV = negative predictive value, PPV = positive predictive value, Sens. = sensitivity, Spec. = Specificity.

RESULTS

Subject Characteristics

Detailed anthropometric information of the subjects is shown in **Table 1**. All subjects were referred to the sleep center with suspicion of sleep-related breathing disorders. Recordings only include so-called diagnostic nights without the presence of any therapeutic measures (eg, continuous or autotitrating positive airway pressure).

Equivalence Test

The paired difference, D, of AHI_{est} and AHI_{PSG} was calculated. Testing D against the equivalence limits revealed:

- H_0: D = 5; H_1: D < 5; P = 4.44e-22; t = −16.62
- H_0: D = 5; H_1: D > −5; P = 3.50e-14; t = 10.32

Therefore, equivalence can be claimed. A standard t test of D reveals: P = 2.8e-03, 95% confidence interval = [−1.9153, −0.4236], standard deviation = 2.62.

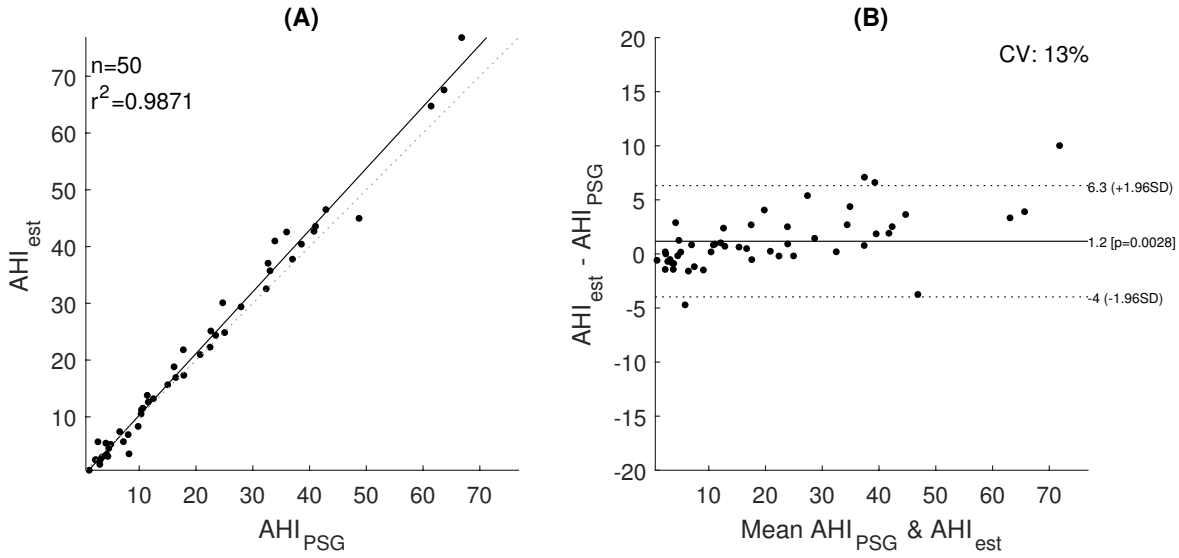
Correlation and Bland-Altman Analysis

Figure 4A shows the correlation scatterplot. This analysis reveals strong correlation between AHI_{est} and AHI_{PSG} (coefficient of determination r^2 = .9871). **Figure 4B** shows the Bland-Altman plot. Using this analysis, a mean ± 1.96 standard deviation difference between AHI_{est} and AHI_{PSG} of 1.2 ± 5.14 is calculated. The coefficient of variation is 13%. The plot reveals a slight negative bias at low AHI (10 to 20 events/h) and a positive bias at high AHI (> 30 events/h).

Sensitivity and Specificity

Using PSG with the total of 50 recordings 4,273 apneas and 1,144 hypopneas are diagnosed. Therefore, the new monitoring system classifies 3,785 apneas and 803 hypopneas correctly (true positive). There were 386 apneas and 156 hypopneas that are incorrectly classified (false positive). Therefore, in 292 cases normal breathing is incorrectly classified as apnea, in 140 cases normal breathing is incorrectly classified as hypopnea, 94 hypopneas are incorrectly classified as apneas, and 16 apneas are incorrectly classified as hypopneas.

Figure 4—Apnea-hypopnea index as measured by the new sleep monitor and polysomnography.



(A) Relationship between AHI measured by the new sleep monitor (AHI_{est}) and AHI measure by polysomnography (AHI_{PSG}). r^2 = coefficient of determination, n = number of data points. **(B)** Bland-Altman plot showing variance between AHI_{est} and AHI_{PSG}, horizontal lines indicate the bias and the limit of agreement (± 1.96 standard deviation), CV = coefficient of variation.

Additionally, the aptitude of the sleep monitor to correctly classify subjects into the groups mild, moderate, and severe OSA is evaluated. Therefore, all subjects are classified into three groups using defined thresholds of AHI ≥ 5, AHI ≥ 15, and AHI > 30 events/h. A detailed performance evaluation is shown in **Table 2**. A Cohen kappa > 0.81 is reached for all groups, which is considered as almost perfect agreement.[20] Using these groups, receiver operating characteristic curves were created and are shown in **Figure 5**. The resulting areas under the curves are 0.9627, 1.0, and 0.9962, respectively. Therefore, it can be claimed that the new sleep monitor is characterized by a high sensitivity and specificity in classifying subjects regarding severity of OSA.

DISCUSSION

The application of a new sleep monitor for automated diagnosis of sleep-related breathing disorders based on tracheal body sound and movement data was demonstrated and its diagnostic capabilities were validated by comparison against standard PSG. The study revealed that the proposed sleep monitor accurately estimates AHI and diagnoses OSA and its severity. A mean ± 1.96 standard deviation difference between AHI_{est} and AHI_{PSG} of 1.2 ± 5.14 was achieved. Consisting only of a small device fixed by a chest belt and a microphone attached to the neck, this new sleep monitor guarantees simple setup, high comfort, and at the same time reduces the effect on sleep quality in comparison with existing ambulatory diagnostic systems.

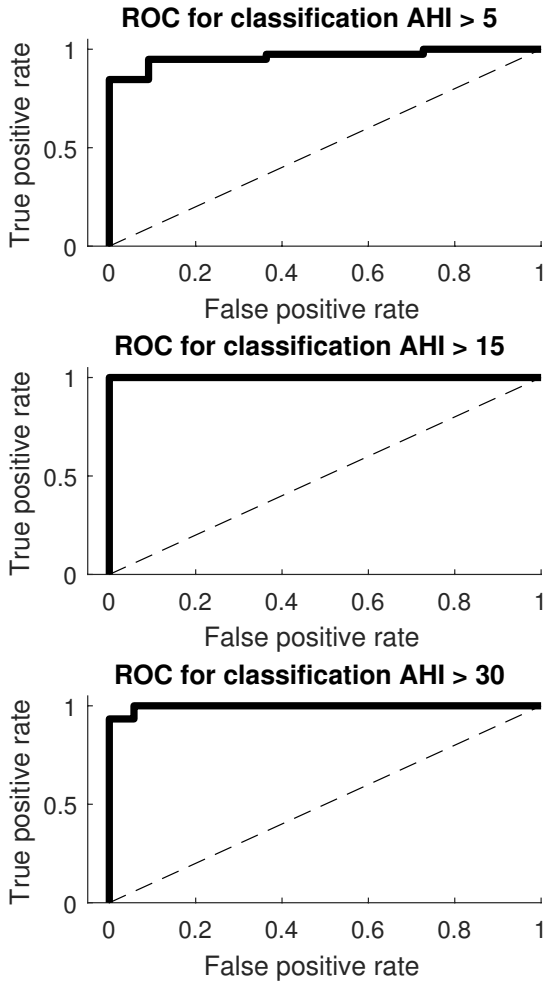
Automated Apnea and Hypopnea Detection

A unique algorithm to automatically calculate AHI was established and described. This algorithm utilizes 3 steps—preprocessing, respiratory drop detection, and classification of apnea and hypopnea—to determine the AHI using the tracheal body sound and movement data. During preprocessing all heart sounds and any noise from the raw audio signal are removed. The drop detection identifies possible apnea and hypopnea events by detecting reductions in breathing amplitude. During classification, the previously extracted events are inspected in detail to distinguish between apnea, hypopnea, and normal breathing. Furthermore, the incorporation of movement data facilitates the detection of motion artifacts and their suppression in the sound signal.

Most commercially available mobile sleep monitors utilize nasal pressure transducers, thermistors, or thoracoabdominal movement belts to record airflow. Even though these methods are the reference standard for measuring breathing, relying solely on one method for the detection of apneas and hypopneas provides poor results compared to the accumulation of measurements carried out during PSG.[21] It is suggested that tracheal body sound provides better results, because it is independent of breathing route and abdominal/thoracic breathing. Nevertheless, body sound recorded at the trachea is affected by individual anatomy.[22] To compensate for this variation, the correlation between sound amplitude and airflow is individually and continuously recalculated.

Of 4,274 apneas and 1,144 hypopneas, the presented algorithm classified 3,785 apneas (89%) and 803 hypopneas (70%) correctly and 386 apneas (9%) and 156 hypopneas (14%) incorrectly. Ninety-four hypopneas (24% of false positive apneas) were incorrectly classified as apneas and 16 apneas (10% of false positive hypopneas) were incorrectly classified as hypopneas. These results reveal the main weakness of the developed algorithm, which is to correctly distinguish between apneas and hypopneas, as well as between hypopneas and reduced but

Figure 5—ROC based on scaling groups mild, moderate, and severe obstructive sleep apnea.



AHI = apnea-hypopnea index, ROC = receiver operating characteristic.

still normal breathing. This bias might be rooted in the fact that the crucial oximetry signal is not available during detection. Without information about oxygen desaturation or arousals the correct classification of hypopneas by definition is inaccurate. However, a study by Rofail et al.[23] suggests that additional oximetry might not necessarily increase the accuracy of OSA diagnosis. Nevertheless, it might be necessary for future funding. Another cause of imprecision is the fact that PSG is evaluated manually and therefore open to the subjectivity of the scoring technician. This bias can hardly be compensated by the detection algorithm and therefore is an additional source of imprecision.

Apnea-Hypopnea Index Estimation

The presented results prove that the new sleep monitor can reliably diagnose OSA. The equivalence test revealed values of $P < .001$ for testing the difference between AHI_{est} and AHI_{PSG} against the equivalence limits. Based on this test, equivalence between AHI_{est} and AHI_{PSG} can be claimed. Furthermore, correlation analysis (see **Figure 4**) revealed a very strong correlation between AHI_{est} and AHI_{PSG}. In addition, when classifying subjects into groups of different severities of OSA the new sleep monitor shows an almost perfect agreement with the PSG. These results clearly outperform previously introduced approaches based on breathing sounds.[12,13,24,25] It is suggested that the predominant limitation of the previous reports is the method of recording audio signals. None of the previously proposed methods utilizes a highly sensitive body sound microphone designed for long-term monitoring of breathing sounds. The provided audio signal represents breathing activity highly accurate and reliable, and therefore improves the detection of apneas and hypopneas. An additional limiting factor of previous studies is suggested to be the disruption of the breathing signal through artifacts and changes in sleeping position. This was demonstrated by Oksenberg and Silverberg[26] by showing that changes in sleeping position have a significant effect on the acoustic features of body sound. This fact restricts previous approaches to only use acoustic features that are minimally influenced by changes in sleeping position. The presented system overcomes this issue by detecting changes in sleeping position and compensating for them during analysis. In summary, the presented method is of strong diagnostic ability in evaluating the severity of OSA and the calculated AHI_{est} shows distinctive agreement with AHI_{PSG}.

Because the study was limited to OSA, it was not possible to evaluate the diagnostic performance of the presented monitor in respect to other sleep-related breathing disorders. It is suggested that the monitor is currently not fit to diagnose other sleep-related breathing disorders. Therefore, it is of immense importance to only use the presented monitor in populations with a high OSA pretest probability. This should reduce the number of false-positive diagnoses and avoid false-negative diagnoses for patients suffering from other sleep-related breathing disorders who are better suited for PSG.

Similar to the presented sleep monitor, other ambulatory type 4 monitors are also simplified devices consisting of 1 or 2 channels.[9] Systematic reviews for the diagnostic performance of those monitors revealed poor results.[27,28] In general, an application of those devices for the definite diagnosis of OSA is not recommended.[8] The commonly used type 3 monitors (at least 4 channels, usually including electrocardiography, airflow, effort, oximetry) provide positive results for the diagnosis of OSA compared to PSG.[28,29] The diagnostic performance of the presented monitor, however, is superior to type 4 monitors and comparable with type 3 monitors. It is therefore suggested that the presented monitor is capable of at least providing a type 3 quality diagnostic accuracy while maintaining a simplified and comfortable setup including only a single lead (body sound microphone) similar to a typical type 4 monitor. Additionally, the evaluation can be fully automated. In addition to saving time, this feature might enable non-sleep specialists, such as family practitioners, to carry out a simple OSA diagnosis. Furthermore, it is suggested that the presented sleep monitor can be used for therapy control in patients in whom a diagnosis has already been made. Nevertheless, this is currently not part of the presented study and therefore more research is required to further examine those suggestions.

Study Advantages and Limitations

The setup of the new sleep monitor and the PSG was performed by trained medical staff. Both recordings were performed concurrently. Four in 60 recordings had to be discarded due to a significant amount of data being lost or unusable. Of these, only one recording was discarded because of a failure of the new monitoring device. The remaining recordings were unusable for validation due to a failure of the PSG itself. This provides promising advantages such as simple and reliable setup and operation of the new sleep monitor without training and medical knowledge. Therefore, the applicability of the developed hardware in home monitoring is suggested. In a home setting, studies will be necessary to fully validate this suggestion.

Because recordings only include diagnostic nights without the presence of any therapeutic measures, all subjects visited the sleep center for the first time. It is suggested that the unfamiliar environment paired with the extensive recording equipment has led to a high level of wake after sleep onset and therefore to an unusual low total sleep time compared to normal sleep time.

All subjects of the current study were recruited with suspicion of sleep apnea and all recordings were carried out in a clinical environment. Therefore, it is suggested that the presented results may be limited to only be applicable to these populations. Because the presented monitor should be primarily used for home screening, the participants might not be an appropriate representation of the target group. Nevertheless, the spectrum of subjects comprises forms of no OSA up to severe OSA. Additionally, the new sleep monitor provides stable results for all participants. However, these findings may be somewhat limited by the small number of females (n = 19) included in this study. Therefore, further studies are required to fully validate the proposed method in a more diverse subject population and a home setting.

Another note of caution is due here because the utilized PSG only used a thermistor to measure airflow. It is suggested that this causes a slight underestimation of AHI.[30] The incorporation of a nasal transducer that allows for a more accurate assessment of airflow to avoid this bias is therefore highly recommended in future studies.

Outlook

One major drawback of the presented monitor is the missing oximetry. A reasonable approach to tackle this issue while keeping the monitor and its setup simple could be to integrate the oximetry measurement into the cone of the body sound microphone. This approach would add another channel to the monitor without affecting the setup or adding any additional leads. Current experimental investigations within our research group are carried out to evaluate the possibility to detect desaturations and pulse at the neck.

A brief analysis of the collected IMU data revealed that pulmonary ventilation movements are captured in the acceleration and velocity signals. This is because the IMU is placed at the upper respiratory inductance plethysmography bands of the subject. Furthermore, it is even possible to capture small vibrations of the chest caused by snoring. Therefore, it is suggested that the IMU data could be utilized to support snore detection in the audio signal and to distinguish between OSA and central sleep apnea. Nevertheless, this is currently not part of the proposed method and therefore more research is required to further examine those assumptions.

Previous work[15,31] revealed that it is also possible to calculate heart rate using tracheal body sound. Recording heart rate using the most common methods (eg, electrocardiography, pulse wave) requires additional sensors or electrodes and wiring. In contrast, the new sleep monitor can record heart rate without the need for further hardware and independent of sex, age, or BMI of the subject using the proposed simple setup. Previous research has established that it is possible to assess information about sleep stages using heart rate variability.[32–34] Knowledge about sleep stages is essential to estimate sleep quality and diagnose different sleep-related disorders. An important outlook of the ability to measure heart rate is the possibility to evaluate sleep stages using the proposed sleep monitor and therefore improve the diagnostic abilities in sleep monitoring significantly. Further research should be undertaken to investigate these suggestions.

CONCLUSIONS

OSA is one of the most common sleep disorders; in addition, there is an alarming number of untreated patients. Therefore, significant effort has been expended to reduce the number of untreated patients by developing simpler but still reliable diagnostic systems.[35] The current gold standard PSG assesses patients with an overnight stay in a sleep laboratory, but high costs and limited sleep capacities result in long waiting periods for patients worldwide. Although at-home sleep monitoring is possible, the application of current methods is constrained by reduced diagnosis abilities, complicated setup for patients, and persistent high costs.

A new comfortable and simple sleep monitoring system for the automated diagnosis of OSA using tracheal body sounds and movement data is proposed and validated using PSG. In conclusion, the current study provides evidence that the proposed sleep monitor can accurately calculate AHI and diagnose presence and severity of OSA. The utilized minimalistic approach can address the need for a simple but reliable diagnosis of OSA. However, its application for home screening, the most important field of application for the proposed monitor, is not yet validated. Therefore, additional studies need to be carried out to ensure reproducibility and applicability in a home setting. To further improve the significance of these studies, patient outcomes should be investigated in addition to AHI.

ABBREVIATIONS

AHI, apnea-hypopnea-index
BMI, body mass index
CI, confidence interval
CV, coefficient of variation
ODI, oxygen desaturation index
ET, evaluation time
IMU, inertial measurement unit

NPV, negative predictive value
OSA, obstructive sleep apnea
PPV, positive predictive value
PSG, in-laboratory polysomnography
ROC, receiver operating characteristic
SpO_2, peripheral oxygen saturation
T90, time while $SpO_2 < 90\%$.
TST, total sleep time
WASO, wake after sleep onset

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