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Determination of sleep and sleep-disordered breathing with minimal- and non-contact technologies

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Preface

All results of this dissertation were published in advance in the following papers:

1. Dietz-Terjung, S., Geldmacher, J., Brato, S., Linker C-M, Welsner M, Schöbel C, Taube C, Götze J, Weinreich G. A novel minimal-contact biomotion method for long-term respiratory rate monitoring. Sleep Breath (2020). https://doi.org/10.1007/s11325-020-02067-4.

2. Terjung S, Geldmacher J, Brato S, Werther S, Teschler H, Taube C, Götze J, Weinreich G. Classification of sleep and wake using a novel minimal-contact single-channel device. Somnologie (2018) 22: 144. https://doi.org/10.1007/s11818-017-0139-z.

3. Weinreich G, Terjung S, Wang Y, Werther S, Zaffaroni A, Teschler H. Validation of a non-contact screening device for the combination of sleep-disordered breathing and periodic limb movements in sleep. Sleep Breath. 2018 Mar; 22(1):131-138. doi: 10.1007/s11325-017-1546-x.

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Content

1 Aim

The aim of the presented work was a) the development of contactless or minimal-contact methods by means of new algorithms and b) the validation of these methods against the diagnostic gold standard PSG. The development of such telemedical procedures could bring us closer to a more patient-centered care in the home environment.

2 Introduction

With technological evolution, development of medicine has also made great strides towards personalized medicine including the application of telemedical approaches. Various studies have shown the benefits of telemedical applications in terms of patient-centered outcome (e.g. through increased compliance with therapy and more self-determination by patients), reduction of costs and increasing access to medical care for patients with chronic diseases especially in underserved or rural areas as well as in low income countries [2, 11, 22, 31, 38].

Telemedicine is currently defined as “the use of electronic information and communication technologies to provide and support health care when distance separates patient and health care unit or professional” [22] by the means of all kinds of telecommunication tools including smartphones, wireless devices for OOC testing, video and telephone consultations. Of note, telemedicine has already found its way into the area of sleep medicine with a variety of implications [2, 3, 4, 8, 11, 14, 16, 22, 24, 31, 38,].

In healthy adults sleep is characterized by a sequence of sleep stages with light, deep and Rapid Eye Movement (REM) sleep in repetitive cycles. The activity of the metabolic, the immune and the autonomous system is closely connected with these sleep stages [29].

Sleep-disordered breathing (SDB), especially obstructive sleep apnoea (OSA), is common in the general population [1, 10, 17, 29, 25, 34-35, 37, 39-40]. Current epidemiological studies show a sharp increase in the prevalence of SDB, so that it can be considered a public health problem. In Germany or Switzerland, for instance, 29.7% of all men and 13.2% of all women are suspected to suffer from moderate to severe sleep apnoea, and thus need a specific treatment [17, 37]. Other previous studies reported that 14% to 47% of the general population had SDB [17, 34, 39-40]. OSA is characterized by repetitive partial or complete collapses of the upper airways leading to repeated arousals and activation of the sympathetic nervous system resulting in altered heart rate variability, generally increased heart Rate (HR) and respiration rate (RR), decreased cardiac vagal outflow and increased blood pressure. Patients with untreated SDB often complain of snoring, non-restorative sleep or daytime sleepiness, which can increase the risk of road traffic accidents [29]. SDB is also a long-term risk factor for cardiovascular and cerebrovascular diseases like heart failure or stroke [15, 19, 23 and 36].

In sleep medicine, the number of apnoeas and hypopnoeas per hour (apnoea- hypopnoea index, AHI) of sleep is used as clinical marker for the severity of SDB with AHI ≥ 5/h as threshold for this disorder. The severity is further graded into mild (5/h ≤ AHI < 15/h), moderate (15/h ≤ AHI < 30/h) and severe (AHI ≥ 30/h).

However, therapy for mild sleep apnoea is only necessary in case of existing cardiovascular risk or associated daytime sleepiness [15, 19 and 23]. Due to limited diagnostic capacities, a high number of unrecognized cases have to be assumed [17, 34, 39-40].

Diagnostic gold standard known as cardiorespiratory PSG [12] is performed in specialized inpatient sleep laboratories. A PSG is a digital measurement with the following parameters being recorded: electroencephalography (EEG), electrooculography (EOG), submental and leg electromyography (EMG) and electrocardiography (ECG). Thoracic and abdominal respiratory movements are recorded using respiratory inductance plethysmography (RIP) and respiratory flow is measured using a nasal cannula. Oxygen saturation is determined by means of pulse oximeter. Thus, a PSG is a cost-intensive approach and moreover an uncomfortable and impeding measurement for the patient, which can only be carried out by qualified personnel in a certified sleep laboratory.

Patients often feel stressed during such a sleep examination due to cables put on their bodies and the unfamiliar sleep environment. Furthermore, a single night examination is not feasible for the detection of changing sleep patterns in short- or long-term [3, 4, 12 and 30].

Early detection and examination of sleep disorders is an important clinical task, as an undetected and therefore untreated SDB is associated with high direct and indirect costs [1, 15, 27, 29 and 36]. The economic implications of SDB are significantly underestimated [1]. In 2016, Frost and Sullivan showed, that for example in the USA, the estimated burden of cost for undiagnosed OSA was $149.6 billion [15]. The authors estimated that additional $49.5 billion would be necessary to diagnose and treat every American adult who has OSA. In Germany, the diagnosis of SDB is performed according to a Bottom-up, step-by-step diagnosis starting with a 6-channel portable monitoring (Polygraphy = PG) at home, followed by a PSG in the sleep laboratory. In other countries, however, other home testing devices with different and/or fewer channels are used, followed by in- or out-lab PSG.

These home testing devices can be classified according to SCOPER classification [4]. This proposed system categorizes OOC devices based on measurements of **s**leep, **c**ardiovascular, **o**ximetry, **p**osition, **e**ffort, and **r**espiratory (SCOPER) parameters. Categorization is based on the number of EEG electrodes used for sleep measurement, the number of ECG recordings and RIP belts, the type of position determination (e.g. use of video recording) and the type of respiration measurement (thermistor or nasal cannula) (Table 1).

Sleep	Cardiovascular	Oximetry	Position	Effort	Respiratory
S_1 - Sleep by 3 EEG channels with EOG AND chin EMG	C_1 – more than 1 ECG lead- can derive events	O_1 - Oximetry (finger or ear) with recommended sampling	P_1 – Video or visual position measurement	E_1 – 2 RIP belts	R_1 – Nasal pressure and thermal device
S_2 – Sleep by less than 3 EEG with or without EOG or chin EMG	C_2 – Peripheral arterial tonometry	O_{1x} – Oximetry (finger or ear) without recommended sampling (per snoring manual) or not described	P_2 – Non-visual position measurement	E_2 – 1 RIP belt	R_2 – Nasal pressure
S_3 – Sleep surrogate: e.g. actigraphy	C_3 – Standard ECG measure (1 lead)	O_2 – Oximetry with alternative site (e.g. forehead)		E_3 – Derived effort (e.g. forehead vs. pressure, FVP)	R_3 – Thermal device
S_4 – Other sleep measure	C_4 – Derived pulse (typically from oximetry)	O_1 – Other Oximetry		E_4 – Other effort measure (including piezo belts)	R_4 – End-tidal CO_2 ($ETCO_2$)
	C_5 - Other cardiac measure				R_5- Other respiratory measure

Table 1: The SCOPER classification
EEG: electroencephalography; EOG: electrooculography; EMG: electromyography; ECG: electrocardiography; RIP: respiratory inductance plethysmography.
Proper oximetry sampling is defined as 3 s averaging and a minimum of 10 Hz sampling rate (25 Hz desirable).
3 EEG channels defined as frontal, central and occipital.
Table adapted from Collop et al. 2011.

However, new OOC devices for SDB detection using parameters according to SCOPER must also be certified according to regulation for medical devices as well as validated against the diagnostic gold standard of PSG in order to prove clinical applicability before they can be implemented for patients’ use.

Patients with SDB have different phenotypes, individual needs, preferences and attitudes that can have a significant impact on treatment decisions.

Recent studies showed that SDB severity shows a considerable night-to-night variability in patients, suggesting that a one-night measurement is not appropriate to estimate SDB severity [24-25, 29]. OOC devices could be a beneficial addition to the already existing patient pathway, since they are suited for long-term use. In contrast to one-night PSG measurements in the sleep laboratory, OOC devices are able to determine night-to-night variability in SDB severity.

Furthermore, the usage of wearables, devices and apps for the long-term monitoring offers opportunities for a more distinct commitment and empowerment of patients. This could be an important step to an improved long-term adherence in means of specific treatments for SDB.

A more accurate diagnostic approach in OOCC testing [4] could significantly reduce invested efforts and associated costs. Hence, smarter diagnostic devices integrating automatic data processing algorithms could enable a more accurate detection of SDB in the home setting without a time, personnel and cost consuming PSG examination. Certainly, PSG will be still an essential technology in future, especially for patients with complex comorbidities. But, new diagnostic approaches could lead to a more efficient utilization of existing sleep lab capacities for patients desperately requiring those resources as current waiting times for a PSG examination are quite long (for example 4 months on average in Germany before the onset of the corona pandemic [20]). An increase of diagnostic accuracy of OOC testing by improved diagnostic techniques compared to gold standard PSG could help to narrow the gap between the high prevalence of SDB and currently limited diagnostic capacities.

In the work presented here, both a contactless and a minimal-contact device were investigated with respect to the diagnostic accuracy in the estimation of sleep and sleep-related parameters.

3 Material and Methods

3.1 Polysomnography

Polysomnography was performed using a digital polysomnograph (Embla, Broomfield, USA) including electroencephalogram (EEG), electrooculography (EOG), submental electromyography (EMG), tibialis EMG, rib cage and abdominal respiratory inductance plethysmography (RIP), pulse oximetry (Nonin 8500, Minnesota, USA), nasal cannula (measurement of respiratory flow at a sample frequency of 20 Hz), and body position. An apnoea was defined as a reduction of respiratory flow for ≥ 10 s and a hypopnoea as a reduction of ≥ 50% in respiratory flow amplitude according to the definition of the AASM [35].

Sleep-disordered breathing (SDB) is a generic term for a range of disorders, with most falling into the categories of obstructive sleep apnoea (OSA), central sleep apnoea (CSA) or sleep-related hypoventilation. OSA was characterized by narrowing of the upper airway that impairs normal ventilation during sleep.

In contrast, central sleep apnoea (CSA) is defined as diminished or absent breathing effort for 10 to 30 seconds either intermittently or in cycles, and is usually associated with a reduction in blood oxygen saturation

Cheyne-Stokes respiration (CSR), a special form of the CSA, was defined as ≥ 3 episodes of continuous cycles of waxing and waning tidal volumes separated by central apnoeas or hypopnoeas with a cycle length of about 40 seconds.

Periodic limb movements in sleep (PLMS) were defined as repetitive movements, most typically in the lower limbs, that occur about every 20-40 seconds.

All recordings were analyzed by experienced investigators. The apnoea- hypopnoea index (AHI) was defined as the number of apnoeas and hypopnoeas per hour of sleep. According to the recommendations of the American Academy of Sleep Medicine, minimum and maximum limb movement (LM) duration was defined as 0.5 and 10 s, respectively. To define a PLM series, a minimum number of four consecutive LM events were required [35]. LMs with close temporal relation to apnoeas or hypopnoeas were not scored as PLM. The PLM index (PLMI) was defined as the number of PLM events per hour of sleep. The newly introduced sleep disorder index (SDI) was defined as the sum of AHI and PLMI.

3.2 SleepMinder^{TM}

SleepMinder^{TM} (ResMed Sensor Technologies, Dublin, Ireland) is a non-contact device based on the Doppler Effect that is capable of measuring the body and breathing movement of sleeping subjects. The device is placed at a maximum distance of 1 meter next to the bed, in a manner that it is approximately 0.25 to 0.5 m above the mattress, directed towards the torso of the patient to be monitored. This technique is based on the reflection of radio waves at a low power frequency band of 5.8 GHz and their phase differences because of a moving object [5]. The SleepMinder^{TM} (SM) device transmits two pulses, the first pulse is called main transmit pulse; the second pulse is the mixing pulse. The main transmit pulse is reflected at nearby surfaces whereby an echo pulse is generated which is received by the sensor. By multiplying the echo pulse with the mixing pulse a signal is generated which is proportional to the occurring phase shift of the echo pulse. Moving objects (e.g. a person breathing or moving in sleep) produce a variable phase shift which can be detected. Additionally, a technique to overcome a known limitation in frequency sensing called the range correlation effect is used. This refers to the fact that, when a moving object makes small movements in the middle of a location with a fixed phase relationship to the sensor, the movements are poorly detected. The technique known as quadrature detection effectively means that there are two types of transmission, resulting in two estimates of motion, called I (in-phase) and Q (quadrature component) channels [5].

The motion signals received in this device contain a mixture of all movements within the field of the sensor. For example, if a person turns around, the received signal will reflect components of all movements, for example limb and head movements. Fortunately, most movements during sleep are related to the effort of breathing, which is used for sleep monitoring [9]. The sensor system outputs two analog voltage signals representing the I- and Q- signals of the sensor. These signals can be linked directly to the PSG system, yielding the possibility of synchronization with other PSG signals. According to the SCOPER classification for OOC testing, SleepMinder^{TM} can be evaluated as $S_4P_2E_4C_5$ method [4]. This means that sleep, body position, respiratory effort and cardiac activity are determined by means of surrogate parameters and that no oximetry is part of the measurement. This is due to the fact that this device measures contactless.

This device has been investigated in previous studies based on various sleep laboratory cohorts indicating a strong correlation to the AHI, Total Sleep Time (TST) and Sleep Efficiency (SE) measured by the gold standard PSG. However, we noticed that patients with comorbid periodic leg movements during sleep (PLMS) shows significantly higher bias in the estimation of these sleep parameters compared to patients without this additional condition. Additionally, a bachelor thesis performed in our clinic showed that the sum of AHI determined by PSG plus Periodic Limb Movement Index (PLMI) correlates strongly with the AHI estimated by SleepMinder™ in patients with PLMS. Therefore, the hypothesis was proposed that for devices based on movement measurements, a combined sleep disturbance index (SDI) derived from the sum of AHI and the PLMI measured by PSG would be more appropriate for comparative analyses.

3.3 Vitalog®

VitaLog® (SWG Sportwerk GmbH & Co. KG, Dortmund, Germany) is a minimal-contact bio motion device that is placed under the mattress topper. The measured data can be directed into the PSG system. The VitaLog® sensor measures body movements, thoracical and abdominal movements, limb movements, respiratory rate as well as heart rate. Based on the SCOPER classification for OOC testing VitaLog® can be classified as $S_4C_5P_2E_4$ device, which means that sleep, cardiac activity, body position and respiratory effort are determined by means of surrogate parameters und no oximetry is performed, which is due to the low-contact measurement. For sleep-wake estimation analysis, the signal is separated into 30 s epochs in accordance to PSG standard. For each epoch, several parameters, including the HR (the average heart rate for the epoch), the activity level, which is an indicator for the amount of body movement during the epoch, are determined to decide whether the person is in bed.

Additionally, each epoch is classified as sleep or as wake based on the activity level using a modified Gorny algorithm (Gorny et al. 1997): An epoch is classified as sleep if the weighted combination of the activity levels of epoch i-6 to i+6 yields a sleep probability that is higher than a predefined threshold. Based on these epochs total sleep time (TST), sleep efficiency (SE), sleep latency (SL) and wake time after sleep onset (WASO) can be calculated in accordance with the 2017 AASM guideline [7, 32].

3.4 Statistics

Methods of descriptive statistics (frequency, mean ± standard deviation, range) were used for analysis of the measured variables. We performed Pearson and Spearman correlation analysis, calculations of sensitivities, specificities, positive predictive values (PPV), negative predictive values (NPV), positive likelihood ratio (LR+), negative likelihood ratio (LR−) and constructed Bland-Altman plots. The Mann-Whitney U test was used to analyze the significance of the agreement of the examined distributions. Statistical analysis was performed using Matlab 2017a (The MathWorks, Inc., Natick, Massachusetts, USA) and SPSS 22.0 (IBM SPSS Statistics, Armonk, New York, USA).

A p value < 0.05 was considered to be statistically significant [7, 32, 35].

3.5 Patients

We examined the two devices on different study populations (table 1, 3, 5). All patients were submitted to the Center for Sleep and Telemedicine at the University Hospital Essen because of SDB. Minors and pregnant patients were excluded in accordance with the Declaration of Helsinki (2013). Patients whose Total Sleep Time was less than 180 minutes were also excluded [7, 32, 35].

A detailed description of the demographic composition of the studied collectives can be found in the results section.

4. Results

In the presented work two different non-contact or minimal-contact sensor systems for home-based estimation of sleep and sleep-related parameters were investigated in representative sleep laboratory collectives.

One of the analyzed sensor systems was the SleepMinder^{TM} device.

We analyzed the diagnostic accuracy of this device in a collective of fifty-seven patients who were sent to the Center for Sleep and Telemedicine at the University Hospital Essen, Ruhrlandklinik because of suspected SDB [35]. The study population was primarily male and had multiple comorbidities (Table 2). SDB prevalence in the analyzed cohort was 84%, and 60% for AHI cutoff values of 5 and 15/h, respectively. The cut-off values 5 events/ h and 15 events/ h were chosen because they represent threshold values to distinguish healthy individuals from patients with mild respectively moderate graded sleep apnoea.

Fifty-one patients suffered from obstructive sleep apnoea (OSA) and six from central sleep apnoea (CSA) with Cheyne-Stokes respiration pattern (CSR). PLMS prevalence was 32 % and 20% for PLMI cutoff values of 5 and 15/h, respectively.

The ethics committee of the University Duisburg-Essen approved this study and all participating patients provided informed consent.

Table 2. Demographic characteristics of the SleepMinder™ cohort

Parameter	Result
Patients (n)	57
Sex (m/f)	46/11
Age (years)	56.4±14.0
BMI (kg/m²)	29.7 ±5.9
AHI (1/h)	22.9 ± 15.4
PLMI (1/h)	6.3 ± 11.1
TST (min)	318 ± 74
SDI (1/h)	29.3 ± 17.9
Hypertension (n)	26
Coronary artery disease n)	15
Congestive heart failure (n)	4
COPD (n)	3
Asthma (n)	1
Type 1 Diabetes (n)	7

BMI: body mass index; COPD: chronic obstructive pulmonary disease, AHI: apnoea-hypopnoea index, PLMI: periodic limb movement index; SDI: sleep disorder index, TST: total sleep time. [35]

SleepMinder™ (SM) detects the movements of trunk and limbs. Motionless phases are classified as sleep, while phases with much movement are labeled as wake. Based on this classification, the SleepMinder algorithm calculates the respiratory disturbances per hour of estimated sleep as AHI_{SM}, which is comparable to the AHI derived from PSG (AHI_{PSG}). In the course of our investigations, it became apparent that there is a strong correlation between the values determined by SleepMinder and the sum of the AHI and PLMI determined by the PSG. Therefore, we investigated whether such this sum value, which we named Sleep Disorder Index (SDI), is better suited for such motion measurement based devices.

We found that correlation between AHI_{SM} and AHI_{PSG} was only moderate (r = 0.57) and systemic bias was high (16.8/h) in the examined collective. For all examined cutoff values an adequate sensitivity and specificity was shown (figure 1a and 1b).

A specific data analysis showed that the AHI_{SM} shows significant deviations of AHI_{PSG} especially in patients who suffered from SDB and showed co-existing PLMS. Adding the PSG-derived PLMI to the AHI_{PSG} in order to get the SDI_{PSG}, which is defines as sum of AHI_{PSG} and PLM_{PSG}, a good match to the AHI_{SM} respectively SDI measured by PSG can be shown. Considering the SDI, the correlation between AHI_{SM} and SDI_{PSG} was strong (r = 0.79) and the systemic bias was negligible (0.8/h) (figure 1 c and d).

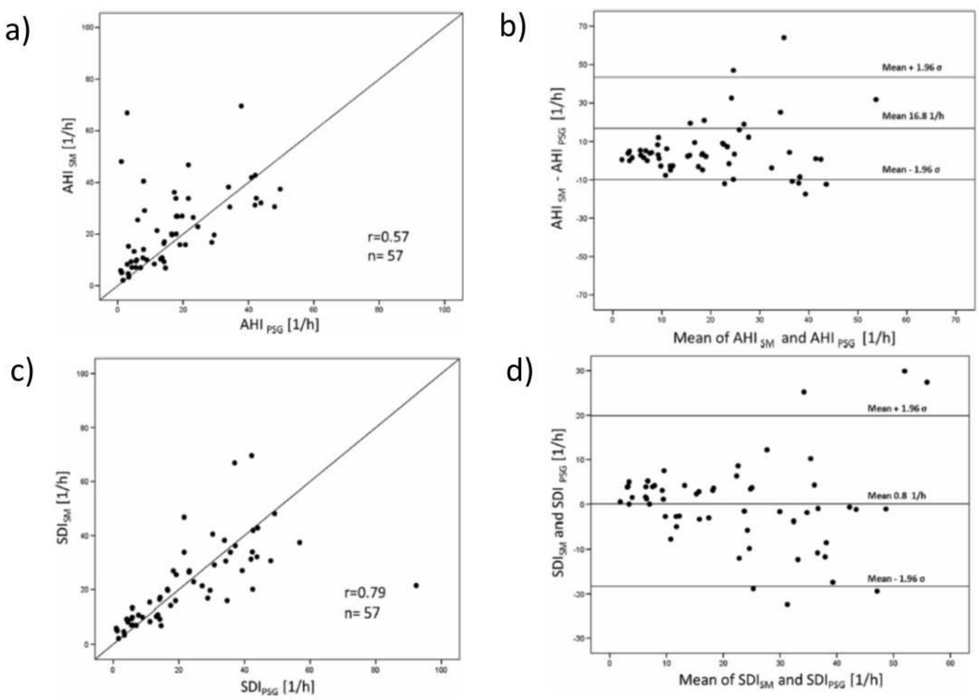

Figure 1: a) correlation analysis and b) Bland-Altman analysis of AHI_{SM} and SDI_{PSG}, c) correlation analysis and d) Bland-Altman analysis of AHI_{SM} and SDI_{PSG} [35].

Additionally, the diagnostic accuracy was high for SDI_{PSG} threshold 15/h compared to AHI_{SM} (Table 3). The performed Man- Whitney-U-analysis showed no statistically significant difference between the two investigated thresholds.

Table 3. The AHI of the non-contact device compared to SDI measured by polysomnography. The sensitivity, specificity, the positive and negative predictive value as well as the positive and negative Likelihood-ratio were calculated to analyze the correlation between the AHI_{SM} and the SDI_{PSG}. The thresholds 5/h and 15/h were used for calculation.

SDI_{PSG}(1/h)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	LR+	LR -
5	98.1/97.9	50.0/41.7	92.7/	80.0 /	2.0	0.04
15	97.2/90.6	95.8/71.0	97.2/	95.8 /	23.3	0.03

SDI: sleep disorder index, PPV: positive predictive value, NPV: negative predictive value, LR+: positive Likelihood ratio, LR−: negative Likelihood ratio [35].

Therefore, we suggest introducing the novel sleep disorder index (SDI) for motion measurement based systems like SleepMinder™.
Unfortunately, this device has been transferred to the lifestyle market, and therefore, scientific further development based on the published results [35] of our study could not been pursued.

Another device investigated in the course of this work was the novel one-channel device VitaLog® (SWG Sportwerk GmbH & Co. KG, Dortmund, Germany). First, we assessed the diagnostic accuracy of this device for sleep–wake classification and measurement of heart rate (HR) in patients with suspected sleep disordered breathing in comparison to the results obtained by PSG.
For sleep-wake estimation analysis, the signal was separated into 30 s epochs in accordance to PSG standard. For each epoch, several parameters, including the average heart rate for the epoch (HR), the activity level, which is an indicator for the amount of body movements during the epoch, were determined to decide whether the person is in bed.
Between September 2016 and March 2017 we included 49 adult patients referred to the Center for Sleep and Telemedicine at the University Hospital Essen due to suspected SDB (table 4). Patients with a PLMI above 5/h were not included into this study to exclude a motion-related confounder on the single-channel measurement system in this proof-of-principle study. Additionally, patients with a TST below 180 minutes were excluded as well to ensure a sufficiently long analysis time. According to the Declaration of Helsinki (2013) all pregnant women were excluded from this study. Analyzed patients were divided into two groups with group 1 containing patients with an AHI <15/h (n=34) and group 2 including patients with an AHI>=15/h (n=15). The distribution was made to analyze, as a first step,

the diagnostic performance of the Vitalog® device in patients with no or mild vs. moderate or severe graded SDB [32].

The ethics committee of the University Duisburg-Essen approved this study and all participating patients provided informed consent.

Table 4. Demographic characteristics of the VitaLog® cohort

Parameter	Result
Patients (n)	49
Sex (m/f)	30/19
Age (years)	56.3±15.2
BMI (kg/m²)	30.3 ± 3.3
AHI (1/h)	14.3 ± 20.4
PLMI (n)	11
Hypertension (n)	27
Coronary artery disease (n)	12
COPD (n)	5
Asthma (n)	6

BMI: body mass index; COPD: chronic obstructive pulmonary disease, AHI: apnoea-hypopnoea index, PLMI: periodic limb movement index (Table adapted from Dietz-Terjung, S. et al, 2020 [7])

The VitaLog® determination of HR was validated compared to HR-analysis out of ECG of PSG in 49 patients with a total of 45,902 epochs, of which an HR estimate was available in 74.5% of the epochs. Per epoch correlation analysis (fig.2 b) showed a correlation of r = 0.99 and a bias of 0.15 beats per minute (bpm).

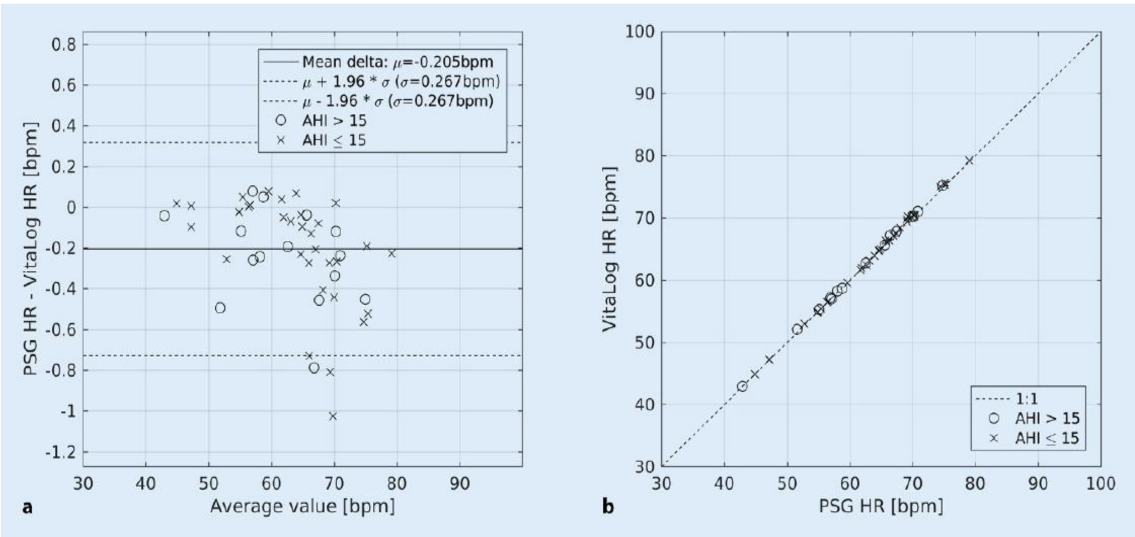

Figure 2: a) Bland-Altman analysis and b) correlation analysis of $HR_{Vitalog}$ and HR_{PSG} [32].

A total of 34 patients were included into group 1 (AHI < 15/h) and 15 patients were referred to group 2 (AHI ≥ 15/h). The overall correlation between $TST_{VitaLog}$ and TST_{PSG} was strong (r = 0.8) with a bias of 14 min. The correlation for the group 1 was r = 0.8 with a bias of 12min, while group 2 showed a correlation of r = 0.6 and a bias of 17min (fig.3).

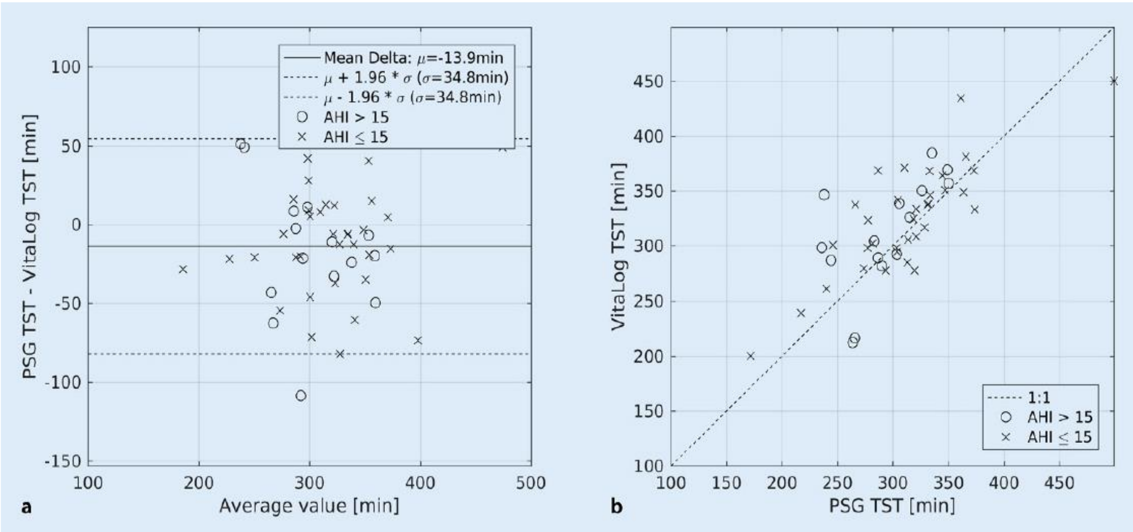

Figure 3: a) Bland-Altman analysis and b) correlation analysis of $TST_{Vitalog}$ and TST_{PSG} [32].

We found an overall correlation of r = 0.6 between sleep efficiency (SE) estimated by Vitalog® ($SE_{VitaLog}$) and SE measured by PSG (SE_{PSG}) as well as a bias of 3.5% (fig. 4). The correlation in group 1 was r = 0.6 with a bias of 3.3%, while group 2 showed a correlation of r = 0.5 and a bias of 4.0%. A comparison of deviations in determination of SE by VitaLog® between the examined groups showed a mean error of 2.6% for group 1 and 4.8% for group 2 (n. s.).

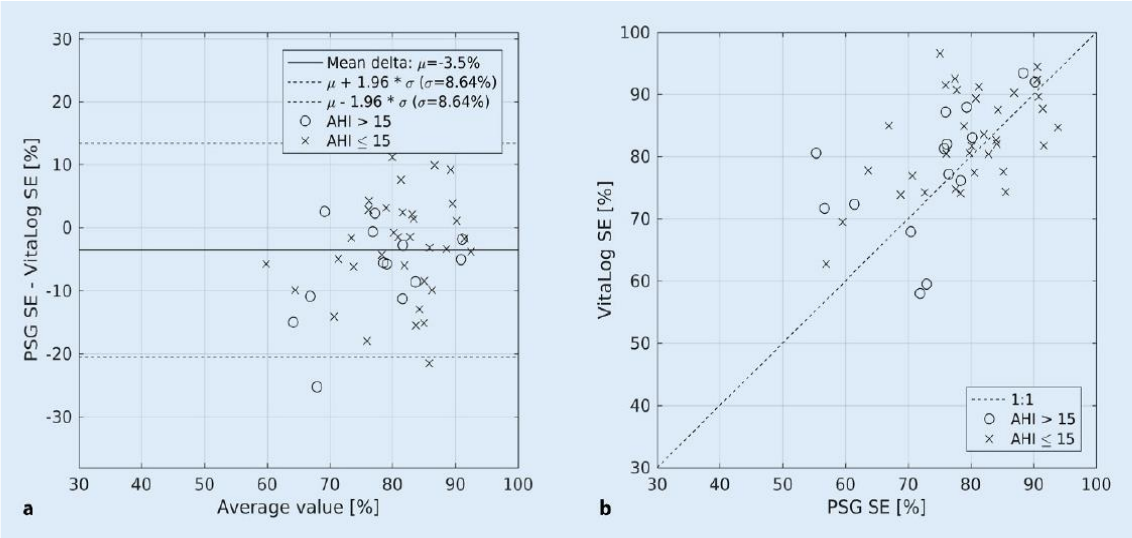

Figure 4: a) Bland-Altman analysis and b) correlation analysis of $SE_{Vitalog}$ and SE_{PSG} [32].

The VitaLog® device showed an overall per-epoch accuracy of sleep–wake classification of 0.83, with a sensitivity of 90%, a specificity of 60%, a positive predictive value (PPV) of 88%, a negative predictive value (NPV) of 65%. The positive and negative likelihood ratio was 3.1 and 0.19, respectively (table 5).

Table 5: Statistic parameter of per-epoch sleep-wake classification

	Accuracy	Kappa coefficient	Sensitivity	Specificity (%)	PPV (%)	NPV (%)	LR+	LR -
All	0.84	0.50	0.91	0.60	0.88	0.67	2.80	0.14
AHI ≤15/h	0.86	0.55	0.93	0.60	0.90	0.68	3.22	0.11
AHI >15/h	0.80	0.45	0.89	0.53	0.84	0.66	2.00	0.20

AHI: apnoea hypopnoea index as measured by PSG, PPV: positive predictive value, NPV: negative predictive value, LR+: positive Likelihood ratio, LR− : negative Likelihood ratio [32].

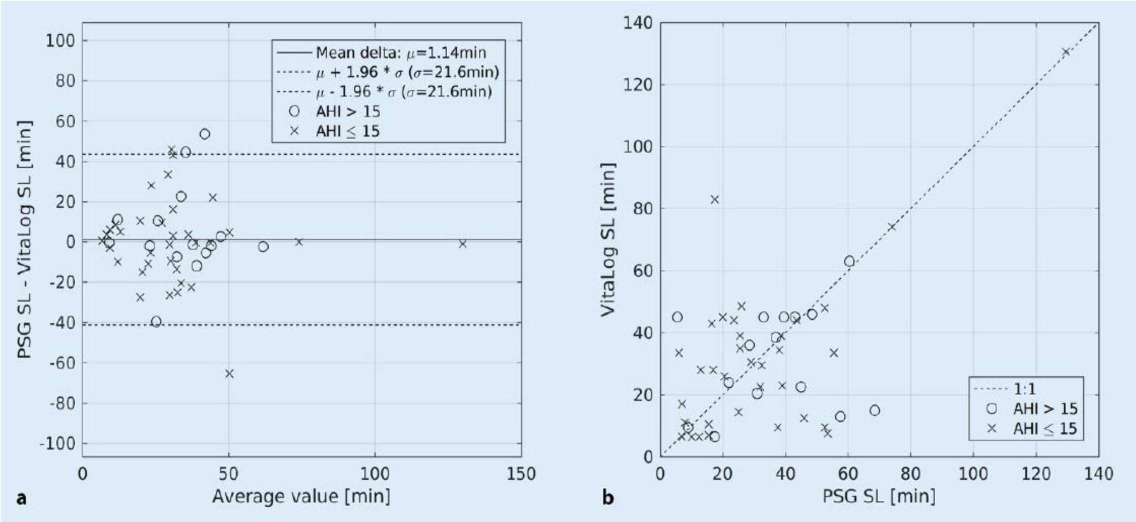

Figure 5: a) Bland-Altman analysis and b) correlation analysis of $SL_{Vitalog}$ and SL_{PSG} [32].

For sleep latency (SL), which is defined as latency to the appearance of the first sleep epoch, a correlation of r =0.6 and a bias of –1.1min was found (fig. 5). The correlation between the estimations for the Wake time after Sleep Onset (WASO), by VitaLog® compared to PSG was moderate (r = 0.5) with an underestimation of 12 minutes (fig. 6).

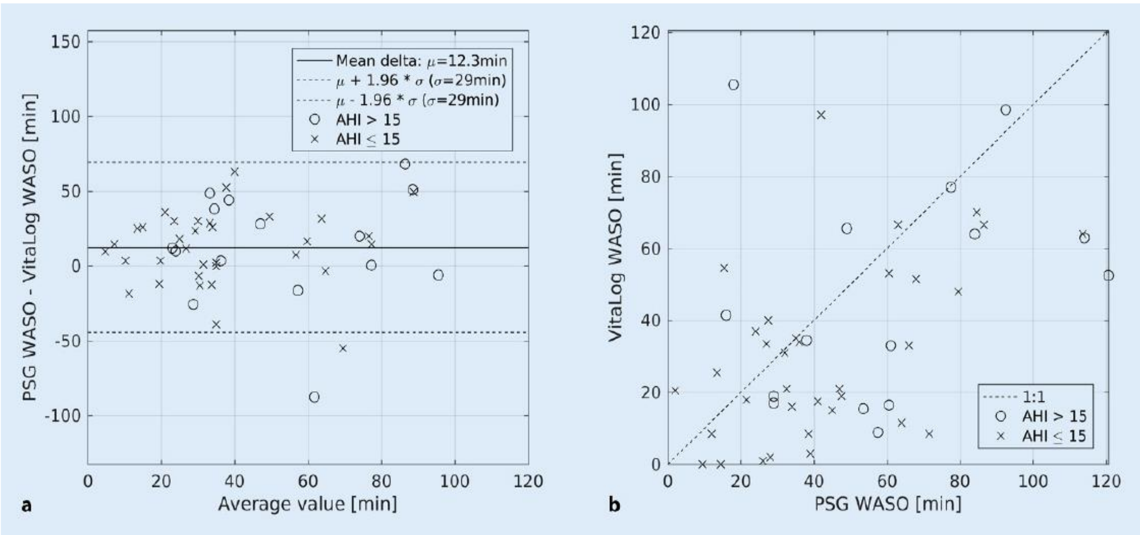

Figure 6: a) Bland-Altman analysis and b) correlation analysis of $WASO_{Vitalog}$ and $WASO_{PSG}$ [32].

Additionally, we analyzed the diagnostic accuracy of VitaLog® for respiration rate (RR) variability estimation. For this sub study, the collective previously used for heart rate and sleep parameter analysis was expanded to 139 patients (table 6). Again, all pregnant women were excluded according to the declaration of Helsinki (2013). A total of 27 patients were excluded due to low sleeping time (TST < 180 min) and 9 patients were also excluded due to a loss of the PSG air flow signal.

We analyzed the diagnostic accuracy of the RR estimation by VitaLog® compared to PSG-derived respiratory rate by nasal airflow for a total of 103 patients (62 men, 41 women) and 75,684 steady 180 s segments (table 5).

Table 6. Demographic characteristics of the VitaLog® cohort

Parameter	Result
Patients (n)	103
Sex (m/f)	62/41
Age (years)	58.2±17.4
BMI (kg/m²)	33.2 ±5.4
AHI (1/h)	16.5 ± 25.3
PLMI (n)	23
Hypertension (n)	56
Coronary artery disease (n)	25
COPD (n)	3
Asthma (n)	13

BMI: body mass index; COPD: chronic obstructive pulmonary disease, AHI: apnoea-hypopnoea index, PLMI: periodic limb movement index; [Table adapted from Dietz-Terjung, S. et al, 2020 [7]

Pearson correlation as well as Bland-Altman analysis of RR estimation was performed in a 180 s window. Firstly, we calculated average values for RR_{PSG} and $RR_{VitaLog}$® and secondly, correlation analysis, finding a strong correlation of r=0.99 and a bias of 0.2 cycles per minute (cpm) (fig. 7).

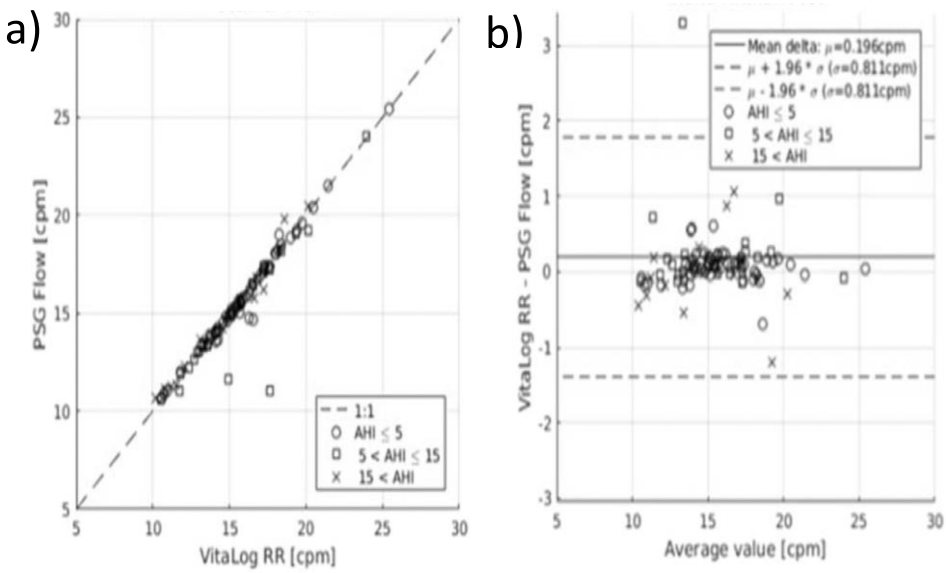

Figure 7: a) correlation analysis and b) Bland-Altman analysis of $RR_{Vitalog}$ and RR_{PSG} [7].

Comparison of different AHI groups showed nearly identical results, indicating that the RR detection algorithm works well in patients with and without SDB using an AHI threshold of 15/h. However, a performed Mann-Whitney U-Test showed no significant difference between the analyzed groups (p>0.05) [7].

5 Discussion

Due to the high prevalence of sleep disorders and the limited number of qualified sleep medical centers the diagnostic capacities are scarce. Therefore, the development and validation of novel technologies enabling a more accurate OOC testing as a preliminary step to PSG is an important research topic in sleep medicine [3, 4, 8].

In OOC testing mobile devices, smart phones or wearables are able to estimate single parameters such as respiration rate, blood pressure, cardiac function or movement. These tools are adapted for home-based monitoring with minimal impairment of sleep. By an increased use of home-monitoring devices sleep centers could be relieved leading to more economical patient pathways and shorter waiting lists [1, 4, 8 and 29].

In general, our findings are comparable to other non- or minimal-contact screening approaches used in out-of-center settings. For example, Dick et al. [6] analyzed the actigraph Somnowatch in a study with 82 patients in a sleep laboratory. The Somnowatch sleep–wake labeling showed a sensitivity of 90.2%, a specificity of 95.2%, and an overall accuracy of 85.9% compared to PSG. The correlations for SE and TST between Somnowatch and PSG were moderate (r = 0.71) to strong (r = 0.89).

Wang et al. [33] analyzed the diagnostic accuracy of wrist actigraphy in order to estimate sleep. The authors found an overall accuracy of 85%, a sensitivity of 95% and a specificity of 41%, which is slightly weaker than the results obtained by the two analyzed devices in our studies.

Kushida et al. [26] examined the diagnostic accuracy of the actigraph AW4 in a cohort of 100 student participants. Regarding the ability to detect sleep, the authors reported a sensitivity of 96%, a specificity of 38% and an overall accuracy of 77% for the whole cohort. The bias for TST and SE was 84 min and 17.5%, respectively.

A study of Hedner et al. [18] investigated an adaptive wrist actigraphy algorithm for sleep–wake assessment in 228 patients with sleep apnoea. For the whole group, the authors found an overall accuracy of 84%, a sensitivity of 89% and a specificity of 69.5%. There was no bias for TST, while SE was underestimated only with 0.4%. Best results were investigated for subjects without and mild OSA.

The study group of De Chazal et al. [5] analyzed the diagnostic accuracy of Sleepminder™. They found an overall accuracy of 78.0%, a sensitivity of 87.3% and a specificity of 50.1% as well as an overestimation of 19min for TST and 4.8% for SE, respectively. Our study confirms the results of De Chazal et al [5], who demonstrated moderate accuracy of the device in estimating TST and SE and showed that SleepMinder™ estimates TST and SE more accurately in patients with an AHI < 15/h.

In our study, there was no statistically significant difference in the estimation of TST and SE between the investigated AHI thresholds. Because our study was a study without case number planning, there is the possibility that there sample size was too small to determine a statistically significant difference. Therefore, an error of second type cannot be excluded. A recent study of Fonseca et al. [12] presented an automatic sleep stage algorithm based on heart rate variability (HRV) and body movements. The classifier showed an accuracy of 75.9 % for four-class sleep staging as well as a strong agreement with a sensitivity of 72.9 % and a specificity of 94.0 % for two-class sleep staging, indicating that the combination of the used features is appropriate for sleep staging compared with PSG. This has been valid for patients both with and without sleep disorders, offering new ways of clinical diagnostics. Lee et al. [28] showed in their study a good consistency in capturing respiratory parameters by a 2.4 GHz radar module in comparison to spirometry assuming that calibration was correct. From the results of this study it can be concluded that devices based on the Doppler Effect, such as SleepMinder™, might also be used for long-term control of the respiratory tidal volume, which is of interest in patients with underlying respiratory diseases such as COPD, asthma, cystic fibrosis or pulmonary fibrosis. All presented results are in line with our findings.

Currently, the SleepMinder™ device fulfil the criteria for a $S_3P_2E_4C_5$ method, while the VitaLog® sensor has to be classified as a $S_3C_5P_2E_4$ method, indicating that these devices are suitable for OOC testing of sleep parameters with adequate reliability and validity.

Therefore, it can be suggested that SleepMinder™ as well as VitaLog® are appropriate devices for long-term use allowing examination of night-to-night variability of sleep-related parameters. The SleepMinder™ device also has the potential to be used in cardiology patients for long-term monitoring of cardiac activity. However, since this device is now used in the lifestyle sector, no further development in this direction was pursued.

Long-term analysis of sleep quality could be a helpful tool not only in sleep disorders, but also in chronic diseases, as disturbed sleep seems to be an important predictor for disease progression [2, 7, 9, 11, 13 and 14].

6 Conclusions

By including cardiorespiratory parameters and detection of body movements contactless or minimal-contact devices for OOC testing can be further improved so that a sufficient sleep diagnostic accuracy could be accomplished in the home-setting as well. This approach is not only able to provide long-term monitoring of sleep disorders and other chronic diseases. Furthermore, the implementation of new telemedicine-based patient pathways may also relieve the diagnostic burden on sleep laboratories. The aim is not to replace PSG, but the usage of new methods might help to ensure that the right patient gets the right diagnostic procedure.

Telemedicine is a logical and important step for sleep medicine. The use of contactless or low-touch remote devices such as smartphones and wearables presented in various studies establishes new possibilities not only in patient-centered care but also in patient empowerment by giving direct feedback. Nevertheless, a structured framework, e.g. the MAST (Model for Assessment of Telemedicine) proposed by Kidholm et al. [8] is necessary to facilitate the choice of the most efficient and cost-effective device for the treating physician. Yet, new devices or sensors developed for medical purposes need to be validated according to legal regulations for medical devices. This includes issues of data security and data privacy.

7 Abstract

Due to the increasing prevalence of sleep-disordered breathing (SDB), the resulting economic burden on healthcare systems and only limited numbers of specialized centers, new technical solutions for diagnostic and treatment become more relevant in sleep medicine. Thus, a more precise out-of-center (OOC) testing could enable a more accurate detection of SDB in the home environment by using smart, non-invasive and non-sleep disturbing, contactless or low-contact diagnostic devices with automatic data processing algorithms.

Methods

The studies presented in this dissertation included patients who were referred to the Center for Sleep and Telemedicine at the University Hospital Essen with suspicion for SDB. The contactless single-channel device SleepMinder™ using radio-frequency technology and the minimal-contact single-channel sensor Vitalog® using piezoelectricity were validated against the diagnostic gold standard of polysomnography (PSG). The results regarding estimation of sleep-wake phases and of other sleep-related parameters were comprehensively analyzed statistically with SPSS 22.0 (SPSS Inc., Chicago, USA) or with Matlab 2017 a (The MathWorks, Inc, Natick, MA, USA).

Results

For both devices a strong correlation for sleep and sleep-related parameters were found. However, regarding the determination of the apnoea- hypopnoea index (AHI) the contactless device SleepMinder™ was found to be inaccurate in case of co-existing sleep-related leg movement disorders.

Discussion

Both devices show promising results for a home-based remote screening for SDB. However, further studies and larger cohorts are required to improve the algorithms.

8 Kurzfassung

Aufgrund der zunehmenden Verbreitung von schlafbezogenen Atmungsstörungen (SBAS), der daraus resultierenden wirtschaftlichen Belastung der Gesundheitssysteme und der begrenzten Anzahl spezialisierter Zentren gewinnen neue technologische Ansätze für Diagnose und Behandlung schlafbezogener Atmungs- (SBAS) und Bewegungsstörungen in der Schlafmedizin an Bedeutung. Eine genauere Erkennung von SBAS in der häuslichen Umgebung der Patienten könnte durch die Verwendung intelligenter, nicht-invasiver, kontaktarmer bzw. berührungsloser – und damit nicht-schlafstörender- Diagnosegeräte mit automatischer Datenverarbeitung erreicht werden.

Methoden

In die Studien der vorliegenden Dissertation wurden Patienten eingeschlossen, die mit dem klinischen Verdacht auf SBAS in das Zentrum für Schlaf- und Telemedizin der Universitätsmedizin Essen, Ruhrlandklinik überwiesen wurden. Das kontaktlose Einkanalgerät SleepMinder™, basierend auf Radiofrequenztechnologie, und der berührungsarme Einkanalsensor Vitalog®, basierend auf Piezoelektrizität, wurden gegen den diagnostischen Goldstandard Polysomnographie (PSG) validiert. Die Ergebnisse der Abschätzung der Schlaf-Wach-Phasen sowie anderer schlafbezogener Parameter wurden mit den Ergebnissen der PSG umfassend statistisch mit SPSS 22.0 (SPSS Inc., Chicago, USA) oder mit Matlab 2017 (The MathWorks, Inc, Natick, MA, USA) verglichen.

Ergebnisse

Für beide Geräte wurde eine starke Korrelation bei der Erkennung von Schlafphasen und weiteren schlafbezogenen Parameter gefunden. Es wurde jedoch festgestellt, dass hinsichtlich der Bestimmung des Apnoe-Hypopnoe-Indexes (AHI) das kontaktlose Gerät SleepMinder™ bei gleichzeitig bestehenden schlafbezogenen Beinbewegungsstörungen einen großen Bias aufweist.

Diskussion

Beide Geräte zeigen vielversprechende Ergebnisse für ein häusliches SBAS-Screening mit telemedizinischer Übertragung der Daten. Weitere Studien und die Analyse größerer Kollektive sind jedoch erforderlich, um die diagnostischen Algorithmen zu verbessern.

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10 Anhang

10.1 Table of Acronyms

apnoea- hypopnoea index	AHI
body mass index	BMI
Chronic obstructive pulmonary disease	COPD
Cheyne Stokes Respiration	CSR
coronary artery disease	CAD
cycles per minute	cpm
cystic fibrosis	CF
electrocardiography	ECG
electroencephalography	EEG
electroocculography	EOG
heart rate	HR
heart rate variability	HRV
Hertz	Hz
idiopathic lung fibrosis	IPF
Giga (10^9)	G
Federal Joint Committee	GBA
in phase- channel	I- channel
Model for Assesment of Telemedicine	MAST
negative predictive value	NPV
Periodic Limb Movement	PLM
Periodic Limb Movement-index	PLMI
Periodic Limb Movement in Sleep	PLMS
positive predictive value	PPV
Polysomnography	PSG
Polygraphy	PG
Out Of Center testing	OOC testing
quadrature component-channel	Q-channel
rapid eye movement	REM
respiration rate	RR
respiratory inductance plethysmography	RIP

Sleep, Cardiovascular, Oxymetry, Position, Effort, Respiration	SCOPER
sleep disordered breathing	SDB
sleep disturbance index	SDI
sleep efficiency	SE
sleep latency	SL
Sleep Minder^{TM}	SM
Total Sleep Time	TST
Wake after sleep onset	WASO

10.2 List of Figuren

10.2 List of Tables

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12 Lebenslauf

Der Lebenslauf ist in der Online-Version aus Gründen des Datenschutzes nicht enthalten.