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ORIGINAL RESEARCH

Validation of a photoplethysmography device for detection of obstructive sleep apnea in the perioperative setting

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Abstract
Obstructive sleep apnea (OSA) is a risk factor for perioperative complications, but many OSA patients present undiagnosed. While polysomnography (PSG) is the "gold standard" for diagnosis, its application is technology-intense, time-consuming, expensive, and requires specialists, often delaying surgery. Thus, miniaturized devices were developed for OSA screening aimed at ruling out major OSA while measuring a lesser number of biological signals. We evaluated the accuracy of a photoplethysmography (PPG)-based device for OSA detection. 48 patients with established or strongly suspected (STOP-Questionnaire) OSA scheduled for surgery underwent in their preoperative nights parallel recordings by PPG and a classic polygraphy (PG) devices (SomnoLab2®). We compared the diagnostic accuracy of the PPG in diagnosing mild [Apnea-/Hypopnea-Index (AHI) 5–14 events/h] and moderate-to-severe OSA (AHI > 15). PPG and PG-derived AHI correlated significantly ($r = 0.85$, $p < 0.0001$) and high area under curve (AUC) in receiver operator characteristics (ROC) values were seen for both AHI thresholds (0.93 and 0.95, respectively). For an AHI > 5, sensitivity was 100%, specificity 44%, positive predictive value (PPV) 62%, negative predictive value (NPV) 100%, likelihood ratio (LHR) 1.79, and Cohen κ was 0.43. For an AHI > 15, sensitivity was 92%, specificity 77%, PPV 60%, NPV 96%, LHR 4.04, and Cohen κ was 0.59. In a typical perioperative cohort of confirmed and suspected OSA patients, PPG reliably detected OSA patients while showing some false-positive results. Such devices are helpful for preoperative OSA screening.

Keywords Anesthesia · Photoplethysmography · Sleep apnea · Screening · Perioperative safety

1 Introduction

Obstructive sleep apnea (OSA), a common sleep related breathing disorder [1, 2] that is characterized by periodic episodes of hypopneas and apneas causing recurrent drops in oxyhemoglobin saturation has a high prevalence among the general population [3, 4]. The prevalence among surgical patient cohorts is believed to be even higher [5] and several studies have shown that OSA is an independent risk factor for perioperative pulmonary complications [6–8]. Hence, OSA patients should be identified before anesthesia, as recommended by the American Society of Anesthesiologists (AHA) [9]. Unfortunately, however, the majority of patients with OSA still presents undiagnosed [10].

The "gold standard" for diagnosing OSA is overnight polysomnography (PSG) in a certified sleep laboratory [11, 12]. PSG, however, requires an overnight stay with a sleep technician in attendance and is, therefore, not only time, labor, and cost intense but may also delay surgery. For this reason, alternative screening tools with a diagnostic accuracy comparable to PSG are desirable. One approach is the implementation of screening questionnaires, like the Berlin questionnaire [13] or the STOP- or STOP-BANG score [14, 15], but some studies showed an unsatisfying accuracy of these tests in some study populations [16, 17]. Nonetheless, these questionnaires can be used to "pre-select" patients at risk for OSA, which could then be further evaluated within the anesthesia community by polygraphy (PG) devices with high accuracy, but a reduced number of channels compared to classic polysomnography [18]. From a clinical viewpoint, these devices should meet several criteria: (1) ease of application and handling, so that a patient could use it at home unassisted; (2) minimum discomfort during sleep; (3) quick

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and easy to interpret data analysis, and (4), most important, high diagnostic accuracy.

Recent guidelines by the American Academy of Sleep Medicine recommend that such polygraphy devices should be used for the diagnosis of OSA in uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA [18]. While several portable devices have been introduced to meet these requirements [19–22], most have to be attached to the patient's chest which compromises sleep comfort.

Accordingly, the present study was designed to evaluate the diagnostic accuracy of a small wrist mounted portable device, the SomnoCheck micro® (SCm, Weinmann, Hamburg, Germany), that uses a combination of nasal air flow detection and different features of the peripheral photoplethysmographic (PPG) signal to detect and differentiate between obstructive and central apneas [23]. Basically, it operates by recognizing the excessive inspiratory decline in the pulse wave evoked by the large inspiratory decrements in pleural pressure as seen with obstructed inspirations. This feature of the device enables it to omit the necessity for abdominal and thoracic straps to detect breathing excursions. Furthermore, and in contrast to other PPG devices [24–26] a nasal cannula is added to detect snoring and nasal air flow in order to improve the detection of respiratory events [23]. We compared the results with this device to the results of an established polygraphy device, the SomnoLab 2 (SL2, Weinmann, Hamburg, Germany), which was applied simultaneously in a typical cohort of surgical patients with established or suspected OSA.

2 Materials and methods

After approval of the local ethic committee adult patients for elective surgery were screened using the STOP questionnaire [14]. Patients with a STOP score of at least 2 or with a pre-existing sleep laboratory acquired OSA diagnosis (but not on CPAP-therapy) were approached for study enrollment. Informed consent was obtained from all individual participants included in the study. Exclusion criteria were neurological comorbidities, cardiac arrhythmias, planned intranasal or intraoral surgery, pre-existing CPAP therapy, pregnancy, or patient refusal.

All included patients underwent simultaneous recordings on the ward with both devices in their preoperative night before surgery and were, therefore, instrumented with two nasal cannulas (one each for the SCm and SL2, respectively). Adhesive tape was used to minimize unintentional cannula displacement. Furthermore, two finger oximeters were placed on the D2 and D4 of the patient's left hand (one for SCm and SL2, respectively). The SL2 was then attached to the chest of the patient with an elastic strap to measure body position and thoracic respiratory efforts. The SCm was attached to the patients` left wrist. Both devices were programmed to automatically start the recordings at 10 pm (after a check that both devices had the same internal clock time) and no sedative medications were allowed. Recordings were automatically terminated at 6 am the following morning. The data was then exported to a PC and analyzed with a dedicated software (SomnoLab® software, Weinmann, Hamburg, Germany) analyzing the raw data of both devices and scanning for respiratory events. All traces were checked manually for artifacts by one of the investigators.

2.1 Respiratory event detection

The main comparison criterion between the two devices was the automatically computed Apnea-/Hypopnea-Index (AHI), i.e., respiratory events per hour.

The definition of an automatically scored apnea was according to the 2007 AASM scoring manual [27]: (1) $\geq$ 90% drop in the air flow amplitude compared to baseline; (2) duration of the event $\geq$ 10 s; and (3) > 90% of the event's duration met the amplitude reduction criteria for apnea.

The definition of an automatically scored hypopnea was: (1) $\geq$ 50% drop in the air flow amplitude compared to baseline together with a 3% oxygen desaturation; (2) duration of the event $\geq$ 10 s; and (3) more than 90% of the event's duration met the amplitude reduction criteria for hypopnea [27].

AHI was then calculated as the number of automatically scored apnea/hypopnea events divided by the recording time.

2.2 Classification of "obstructive" versus "central" events

While the criteria for automatically identification of an apnea or hypopnea were the same for both devices, they used different techniques for the differentiation between central versus obstructive events. With its thoracic strap and its positioning on the patient's chest the SL2 identifies a respiratory event as "obstructive" if respiratory efforts are detected during such an event. In the absence of respiratory efforts, a respiratory event is classified as "central". The SCm distinguishes the type of the apnea ("obstructive" vs. "central") by analyzing the pulse waveform. Briefly, the respiratory effort was detected by analyzing fluctuations of the PPG signal evoked by intrathoracic pressure changes during spontaneous breathing cycles [28].

2.3 Statistical analysis

Analyses were performed using Graphpad Prism® (GraphPad Software, La Jolla, CA, USA). We tested for normal distribution using the D'Agostino–Pearson normality test. Normally distributed data are presented as means ± standard

deviation (SD) and non-normally distributed data are presented as median (95% confidence interval of the median (CI)). To measure the accuracy of the PPG device at detecting OSA we compared the PG derived AHI to the PPG based AHI value at different clinical thresholds of ≥ 5 (mild OSA) and ≥ 15 events/h (moderate OSA). Analysis included measurements of sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratio, Cohen's κ coefficient, area under the receiver operator characteristics (ROC), and correlation analysis. Bland–Altman plots were used for graphic representation of the performance of the PPG in comparison to the PG device and to check for systematic bias.

3 Results

After informed consent 75 patients scheduled for elective surgery were included and instrumented. Twenty-seven of these patients had to be excluded after study enrollment (13 with insufficient recording time because of intentional or accidental removal of at least one of the devices, 14 because of poor data quality of either the flow or the pulse signal).

60.4% of the remaining patients (n = 29) had been included because of at least 2 positive items in the STOP questionnaire. The remaining 39.6% (n = 19) of the patients had a preexisting, sleep laboratory derived diagnosis of OSA but no CPAP-therapy. The patients' demographic data are shown in Table 1.

We tested the capability of the PPG to correctly measure the AHI against the PG and found a strong correlation (r = 0.85, p < 0.0001, Fig. 1). Table 2 summarizes the sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratio, Cohen's κ coefficient, and the AUC for the two clinical AHI thresholds of ≥ 5 and ≥ 15 events/h. When applying the threshold criterion for mild OSA (AHI ≥ 5 events/h) the PPG demonstrated a very strong sensitivity of 100% with a rather low specificity of 44%, a negative predictive value of 100%, a likelihood ratio of 1.79, and a Cohen κ of 0.43, indicating an acceptable agreement between both devices.

Using the threshold for moderate-to-severe OSA (AHI ≥ 15) we found a slightly decreased sensitivity of 92%, with an increased specificity of 77%. The negative predictive value was 96%, the likelihood ratio increased to 4.04 compared to the lower threshold, and Cohen κ was 0.59, again, indicating an acceptable agreement between both devices.

ROC for the two thresholds (Fig. 2) showed high AUC values for both thresholds (0.93 and 0.95, respectively). The Bland–Altman-Plot (Fig. 3) demonstrated a robust agreement between the measurement techniques, with a mean bias of 3.1 and almost all measurement points lying within two standard deviations of the mean bias.

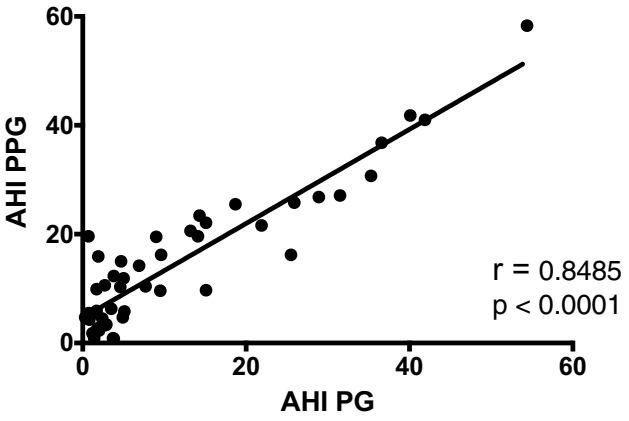

Fig. 1 Linear regression of the photoplethysmography (PPG) derived Apnea-/Hypopnea-Index (AHI) and the AHI measured with the polygraphy (PG). There was a significant correlation between both measurements (r = 0.8485, p < 0.0001)

Table 1 Patient characteristics

Total patient no.	48	
Sex (male/female)	31 (64.5%)/17 (35.5%)	
Age (years)	57 ± 10	
BMI (kg/m^2)	32 ± 6.8	
AHI (events/h)	4.8 (2.8–15.21)	
OSA severity	(as assessed by SL2)	(as assessed by SCm)
No OSA	25 (52%)	11 (23%)
Mild OSA	10 (21%)	17 (35%)
Moderate-severe OSA	13 (27%)	20 (42%)

Data are presented as numbers and percentage, mean ± SD, or median (95% confidence interval of the median)

BMI Body Mass Index, *AHI* Apnoe–Hypopnoe-Index, *OSA* obstructive sleep apnea, *SL2* SomnoLab2, *SCm* SomnoCheck micro

4 Discussion

In a cohort of 48 surgical patients with established or suspected OSA and scheduled for elective surgery, we evaluated the validity of a small, wrist worn photoplethysmography device, that uses nasal air flow and pulse wave characteristics to detect apneic or hypopneic events against a polygraphy device with multiple biochannels.

While demonstrating a significant correlation of the PPG derived AHI and the AHI detected by PG, we also showed high sensitivity values for the PPG at two different clinical OSA thresholds. The specificity, on the other hand, for an AHI ≥ 5 events/h was low (44%), resulting in a low likelihood ratio of 1.79. These values increased to 77% and

Table 2 Performance metrics of the PPG at two clinical AHI thresholds

	Sensitivity	Specificity	PPV	NPV	LHR	Cohen κ	AUC
AHI ≥ 5	100	44	62	100	1.79	0.43	0.93
AHI ≥ 15	92	77	60	96	4.04	0.59	0.95

PPV positive predictive value, *NPV* negative predictive value, *LHR* likelihood ratio, *AUC* area under the curve, *AHI* Apnea–Hypopnea-Index, *PPG* photoplethysmography

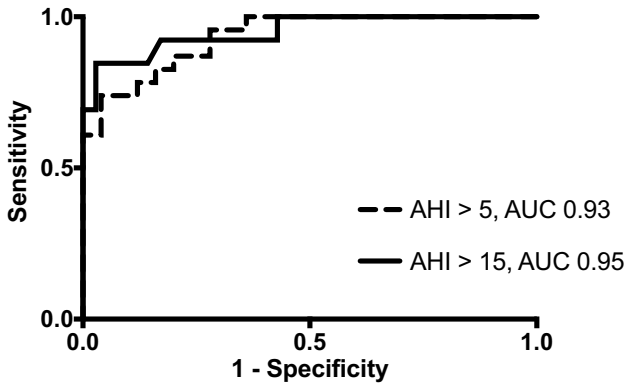

Fig. 2 Receiver-operator characteristics for the Apnea-/Hypopnea-Index (AHI) obtained by photoplethysmography (PPG) versus with the polygraphy (PG) for two different clinical thresholds for obstructive sleep apnea (OSA) severity. The area under the curve (AUC) was high with both thresholds, indicating a high ability of the PPG to discriminate between the individuals with OSA and those without. (Dashed line: mild OSA (AHI ≥ 5), solid line: moderate-to-severe OSA (AHI ≥ 15))

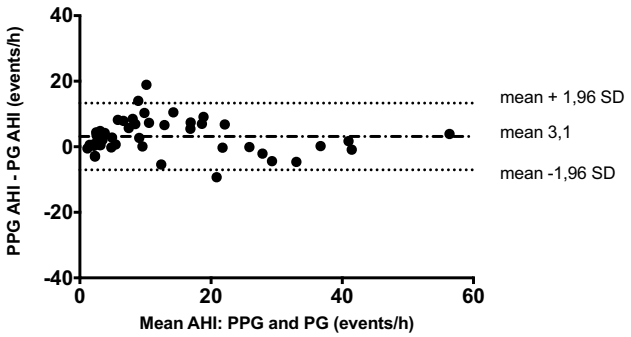

Fig. 3 Mean Apnea-/Hypopnea-Index (AHI) versus difference in AHI between photoplethysmography (PPG) and polygraphy (PG). Central line represents the mean bias of the PPG and the upper and lower lines represent the agreement limits (two standard deviations). All but three estimates lie within these limits

4.04, however, when applying the threshold for moderate-to-severe OSA (AHI ≥ 15 events/h). We also found a high AUC for both thresholds, indicating a great ability of the PPG to discriminate between individuals with OSA (with the respective threshold) and those without.

Compared to other studies we found a higher sensitivity and a lower specificity for PPG when validated against PG/PSG [24–26]. While these groups used different PPG devices, usually without a nasal cannula, it is also important to state, that our patients had an increased pretest probability for OSA, as we only included patients with an established OSA diagnosis or at least two positive STOP items [14].

Considering the high potential for postoperative complications of OSA patients [3, 8, 29] and the high proportion of them presenting undiagnosed [5], a miniaturized device, that measures a small number of biological signals with high sensitivity and a high negative predictive value is useful in reliably detecting OSA patients immediately before surgery, prompting for considerations of an altered perioperative management and a higher degree of postoperative monitoring [3].

The rather low specificity of the PPG for detecting mild OSA, however, may lead to a false-positive OSA diagnosis, what in turn may evoke an unnecessary increased level of postoperative monitoring in non-OSA patients. Therefore, from a practice point of view, an individualized benefit-risk-assessment has to be made whether these patients should be further investigated before surgery or monitored more extensively afterwards. Setting the AHI threshold to ≥ 15 may help identifying by PPG patients suffering from the more severe OSA with a still high sensitivity and an increased specificity. In practice, patient safety must be weighed against the need for economically sensible mobilization of sparse monitoring resources [3].

There are some limitations of our study. First, we had a relative high dropout rate. Our patients were investigated in the night immediately preceding their surgery and some of them felt uncomfortable wearing during sleep two devices simultaneously for scientific reasons only. Second, the SomnoLab2®, which we chose as the reference device for screening also would have allowed full scale PSG. However, we used a reduced signal number (i.e., omitting electromyogram, electroencephalogram, and electrooculogram) since, presumably, the dropout rate would have been even higher, as our patients were not studied in a sleep laboratory but left unattended in their ward room during their preoperative night. Guidelines, however, allow the use of PG for diagnosing OSA in uncomplicated patients with a high pretest probability [18].

In summary, we evaluated PPG by the Somnocheck micro® in a surgical cohort and found a significant correlation of the PPG derived AHI with the PG AHI. While

AUC and overall sensitivity was very strong, specificity was low for an AHI threshold of ≥ 5 events/h but acceptable for ≥ 15 events/h. PPG also proved to be a simple, cost-effective, resource-saving method to identify OSA patients before surgery to potentially adapt their perioperative management. Whether PPG alone can be used for screening avoiding delays in surgery by deferring or omitting classic sleep laboratory studies should be addressed in future studies.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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