



Validation of the oxygen desaturation index in the diagnostic workup of obstructive sleep apnea

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Received: 14 March 2017 / Revised: 2 March 2018 / Accepted: 12 March 2018
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Abstract

Introduction Obstructive sleep apnea (OSA) is common, and diagnosis requires expensive and laborious testing to assess the apnea hypopnea index (AHI). We performed an analysis to explore the relationship between the oxygen desaturation index (ODI) as measured with pulse oximetry and the AHI in our large portable monitoring (PM) database to find an optimal cutoff value for the ODI in order to be able to exclude $AHI \geq 5$ on PM.

Methods Three thousand four hundred thirteen PM recordings were randomly divided into a training set ($N = 2281$) and a test set ($N = 1132$). The optimal cutoff for the ODI to exclude an $AHI \geq 5$ on PM was determined in the training set and subsequently validated in the test set.

Results Area under the curve of the ODI to exclude an $AHI \geq 5$ on PM was 0.997 in the training set and 0.996 in the test set. In the training set, the optimal cutoff to predict an $AHI < 5$ was an $ODI < 5$. Using this cutoff in the test set provided a sensitivity of 97.7%, a specificity of 97.0%, a positive predictive value of 99.2%, and a negative predictive value of 91.4%.

Conclusion An $ODI < 5$ predicts an $AHI < 5$ with high sensitivity and specificity when measured simultaneously using the same oximeter during PM recording.

Keywords Obstructive sleep apnea · Apnea hypopnea index · Oxygen desaturation index · Pulse oximetry

Introduction

The prevalence of obstructive sleep apnea (OSA), defined as apnea hypopnea index (AHI) ≥ 5 events per hour sleep, is high. In the early 1990s, at least 2 to 4% of the middle-aged

population was affected [1], and over two decades this has increased to over 10% [2]. Although it is increasingly recognized, there is still only a small group that has actually been diagnosed with OSA [3, 4].

Prior publication An abstract of this research was presented as a thematic poster during the 2016 ERS congress.

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OSA often requires lifelong treatment with multidisciplinary management. Before initiating treatment, it is important to have an appropriate diagnosis and to know the severity. Therefore, a valid method is necessary to prove or exclude sleep apnea. The diagnosis usually relies on a thorough sleep history and interpreting the clinical symptoms, physical examination, and sleep recording with type III portable monitoring (PM) or polysomnography (PSG) recording according to the algorithm proposed by the 2012 update of the American Academy of Sleep Medicine (AASM) guidelines [5]. Following these guidelines, the oxygen desaturation index (ODI) is defined as the number of desaturations per hour of at least 3% from baseline.

Nowadays, there is an increasing interest in screening for OSA in specific groups like patients in general practice, patients with hypertension, obesity or diabetes, subjects in groups with demanding tasks like commercial drivers, and in the preoperative setting [6]. The prevalence of OSA in these specific groups and the general population is likely to be lower than the prevalence of OSA in patients referred to a sleep center. Therefore, extensive sleep monitoring is too cumbersome and too expensive in these populations [7]. As a desaturation is often present in hypopneas and apneas, it can be hypothesized that the ODI may be used as substitute of the AHI. As oximetry is cheaper and less burdensome than type III PM and PSG, its use (possibly combined with a questionnaire) seems an attractive option to screen for OSA in the general practice and for treatment follow-up (e.g., mandibular advancement device, positional therapy, weight reduction). Modern pulse oximeters have the potential to achieve this [8, 9]. Multiple studies have shown good agreement between PSG- and PM-derived AHI with oximetry alone [9–11]. In setting up a screening study in general practice, we performed an analysis to explore the relationship between the ODI as measured with pulse oximetry and the AHI in our large PM database.

Methods

Study population

The study was conducted at the Medisch Spectrum Twente, Enschede, the Netherlands. The study included all PM recordings performed between January 2013 and December 2015. Exclusion criteria were as follows: age < 18 years; effective recording time < 4 h; missing patient characteristics (age, height, weight); missing AHI, apnea index, hypopnea index, or ODI; and missing conclusion or conclusion “failed measurement.”

Sleep recording

Sleep recordings were all done with the NOX T3 Sleep Monitor (Nox Medical, Reykjavík, Iceland), a

S₃C₄O₁P₂E₁R₂ type III PM device [12] which measures the following signals: nasal flow, effort by inductive belts (thorax and abdomen), oximetry using the Nonin WristOx₂TM model 3150 wrist-worn pulse oximeter (Nonin Medical, Inc., Plymouth, MN, USA), acoustic snoring sound detection, body movement activity, and body position. Raw data were stored in a database, and adaption of the recording time was performed by visual judgment of the pulse rate and body activity or general artifacts in all signals. According to the most recent AASM rules, an apnea was defined as a flow decrease of $\geq 90\%$ and a hypopnea was defined as a flow decrease between 30 and 90% with a desaturation of $\geq 3\%$ [13]. All respiratory events did have a duration of at least 10 s. A PM recording was first automatically analyzed by Noxturnal version 4 (Nox Medical, Reykjavík, Iceland), and all signals (including the respiration and oxygen saturation signals) were subsequently manually assessed by a trained respiratory technician (i.e., hypopneas, apneas, and desaturations were added or deleted when appropriate according to the AASM guidelines). The analyzed results were stored in a database.

Data collection

The data of all available PM recordings from January 2013 to December 2015 were extracted from the database. Hereafter, the data were anonymized and the exclusion criteria were applied.

Ethical considerations

This retrospective study was approved by the Medical Ethical Committee Twente at Enschede, as well by the board of directors of the Medisch Spectrum Twente, Enschede, the Netherlands.

Statistical analysis

The data was randomly divided into two groups: a training set (2/3 of the data) and a test set (1/3 of the data). The training set was divided in a sub-training set (3/4 of training set) and sub-validation set (1/4 of training set). The sub-training set was used to search for the optimal cutoff value for the ODI to predict an AHI < 5 using a receiver operating characteristic (ROC) curve. The diagnostic accuracy (expressed as sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio, negative likelihood ratio, and area under the curve (AUC) of the ROC curve with corresponding 95% confidence intervals (95%CI)) of this cutoff value was subsequently assessed in the sub-validation group. The best cutoff value was then assessed in the test set. Continuous variables are expressed as mean with standard deviation or median with interquartile range (IQR), as appropriate. Categorical variables are expressed as counts with

corresponding percentages. Data were analyzed using SPSS version 22 (SPSS Inc. Chicago, IL, USA).

To be able to assess the characteristics of the recordings with a large difference in AHI and ODI, the data was divided into three sets: those with a large negative difference (i.e., AHI was smaller than ODI, defined as the data below the 10th percentile of the AHI-ODI difference), those with a normal difference (defined as the data between the 10th and 90th percentile of the AHI-ODI difference), and those with a large positive difference (i.e., AHI was larger than ODI, defined as the data above the 90th percentile of the AHI-ODI difference). Differences in characteristics (age, weight, BMI, and signal quality) between the large negative versus the normal group and the large positive versus the normal group were performed with independent samples *t* tests or Mann-Whitney *U* tests as appropriate. A *p* value < 0.025 was considered to indicate a statistically significant difference.

Results

A total of 4154 PM recordings were included. After applying the exclusion criteria, 3413 recordings remained for analysis. Characteristics of the included recordings are provided in Table 1. The recordings were divided into two groups: a training set of 2281 recordings and a test set of 1132 recordings. The training set was divided in a sub-training set of 1705 recordings and a sub-validation set of 576 recordings. Patient characteristics did not differ between the sets (data not shown).

In the sub-training set, the AUC of the ODI to predict AHI < 5 was 0.997 (95%CI 0.995–0.999). From the ROC curve, it was concluded that the optimal cutoff of ODI to predict AHI < 5 was a value of 5 desaturations per hour. Using this cutoff provided a sensitivity of 97.8%, a specificity of 97.4%, a PPV of 99.3%, and a NPV of 91.8%. The diagnostic performance of this cutoff in all sets is provided in Table 2. In the sub-

Table 1 Patient characteristics of the complete dataset

<i>N</i> = 3413	Mean or median	Std (%) or IQR
Age (years)	53.6	13.4
Males (<i>N</i> (%))	2399	70.3
Weight (kg)	92.5	18.6
BMI (kg/m ²)	29.6	5.7
AHI ≥ 5 (<i>N</i> (%))	2726	79.9
AHI (<i>N</i> /h)	12.1	(5.9–23.9)
ODI (<i>N</i> /h)	11.9	(5.7–23.9)

Categorical variables are presented as number with corresponding percentage of the total population. Continuous variables are presented as mean with corresponding standard deviation (Std) or median with corresponding interquartile range (IQR)

validation set, the diagnostic performance was similar to the performance in the sub-training set. AUC of the ODI to predict AHI < 5 in the test set was 0.996. As these values were satisfying, the cutoff of ODI < 5 was finally tested in the test set, which provided a sensitivity of 97.7%, a specificity of 97.0%, a PPV of 99.2%, a NPV of 91.4%, a positive likelihood ratio of 32.1, and a negative likelihood ratio of 0.02. The resulting cross tabulation is provided in Table 3.

A scatter plot of the measured ODI versus the measured AHI is provided in Fig. 1 ($R^2 = 0.99$). Of the 21 false-negative patients, 1.9% of all recordings in the test set, with ODI < 5 but AHI ≥ 5, median AHI was 5.2 with a minimum of 5.0 and a maximum of 8.6. A Bland-Altman plot of the AHI versus the ODI in the test is provided in Fig. 2. Mean difference between AHI and ODI (AHI minus ODI) was +0.21 (95%CI –2.98; 3.41) events per hour.

The test set contained a total of 45,911 apneas (median per recording 10 (IQR 3–35)) of which 2897 (6.3%) were not associated with a desaturation (median per recording 0 (IQR 0–2)). The total number of desaturations was 142,133 (median per recording 84 (IQR 40–162)) of which 6645 (4.7%) were not associated with a respiratory event (median per recording 2 (IQR 1–6)).

Compared with those with a difference in AHI and ODI between the 10th and 90th percentiles, the subjects with recordings with a difference in AHI and ODI below the 10th percentile (i.e., AHI was smaller than ODI) had a significantly higher weight (100.3 ± 18.2 vs 91.7 ± 17.9 kg, $p < 0.001$) and higher BMI (33.0 ± 6.0 vs 29.3 ± 5.5 kg/m², $p < 0.001$) and were older (58.2 ± 12.8 vs 53.0 ± 13.1 years, $p < 0.001$). The signal quality was also significantly lower but the absolute differences were small (99.4 (IQR 97.2–99.8) % vs 99.6 (IQR 98.8–99.9) %, $p = 0.016$).

Compared with those with a difference in AHI and ODI between the 10th and 90th percentiles, the subjects with recordings with a difference in AHI and ODI above the 90th percentile (i.e., AHI was larger than ODI) were significantly older (57.7 ± 13.7 vs 53.0 ± 13.1 years, $p < 0.001$). There were no significant differences in weight, BMI, and signal quality between these groups.

Discussion

The results clearly indicate that with the current assessment criteria, the measured ODI is highly correlated with the measured AHI during PM recordings. Using a cutoff value of an ODI < 5 to exclude an AHI < 5 on PM resulted in only 21 (1.9%) misclassified patients. All of these subjects had an AHI marginally higher than 5. This is visualized in Fig. 1 where almost no circles are present in the upper left quadrant. Given the low false-negative rate (and small negative likelihood ratio), these results suggest that the ODI can safely be

Table 2 Diagnostic performance of ODI < 5 to predict AHI < 5 in the sub-training, sub-validation, and test sets

	Sub-training set (<i>N</i> = 1705)	Sub-validation set (<i>N</i> = 576)	Test set (<i>N</i> = 1132)
Sensitivity	97.8 (96.8–98.5)	98.1 (96.3–99.1)	97.7 (96.5–98.6)
Specificity	97.4 (95.1–98.8)	99.1 (95.1–100.0)	97.0 (93.8–98.8)
PPV	99.3 (98.7–99.7)	99.8 (98.8–100.0)	99.2 (98.4–99.7)
NPV	91.8 (88.5–94.4)	92.5 (86.2–96.5)	91.4 (87.1–94.6)

Data are provided as percentage (95% confidence interval)

PPV positive predictive value, NPV negative predictive value

used to rule out an AHI < 5 on a PM recording, at least in a population referred to a sleep center. As pulse oximetry is less expensive and less time-consuming than PM recordings, it is more suitable as a screening tool.

In the Netherlands, it is standard care that the general practitioner, if the presence of sleep apnea is suspected, refers a subject to a sleep center. The sleep center performs a PM recording or PSG, often in the home setting. Hereafter, the results are discussed with the patient, and the appropriate therapy (continuous positive pressure, oral appliances, positional therapy, or no therapy) is started. We propose that modern pulse oximetry can be used by the general practitioner as an easily accessible screening method. It is important to note that this is only true in the population in which a PM recording is deemed valid. Two recent large randomized controlled trials showed that in the right population (i.e., subjects with a high pretest probability of moderate to severe OSA), PM recording is sufficient for the diagnosis and treatment of OSA [14, 15]. The recent clinical practice guideline of the American Academy of Sleep Medicine also recommends that “polysomnography, or home sleep apnea testing with a technically adequate device, be used for the diagnosis for OSA in uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA” [16]. The population of the current presented data consists of patients in whom the sleep physician deemed PM valid as diagnostic recording. Consequentially, if oximetry would be used as a screening tool for OSA by the general practitioner, this would only be a valid strategy if the right patients are selected for screening. The use of a questionnaire (such as the Philips questionnaire [3]) might enable this selection [17].

The subjects with a high positive difference in AHI and ODI were older, suggesting that the ODI may be less useful to represent the AHI in older patients perhaps due to the presence of relevant comorbidities. Furthermore, the subjects with

a high negative difference in AHI and ODI had a higher BMI and were also older. Both high age and high BMI might cause hypoxemia, which can explain the high ODI compared to AHI. The opposite may also be true: young subjects without cardiopulmonary comorbidities are less prone to desaturations, and therefore oximetry (but also PM recording) is unsuitable to detect OSA in these subjects. Unfortunately, the current database does not cover information on hypoxemia and comorbidities. The influence of several characteristics on the usability of pulse oximetry to resemble AHI should be investigated in further research. However, the number of false negatives (and false positives) seems already acceptable.

When the appropriate patient is selected and the pulse oximetry measurement shows an ODI < 5, the patient should not undergo a subsequent PM recording as the currently presented data show that the probability of an AHI < 5 on a PM is low in these subjects. Instead, a PSG may be performed. The high correlation between ODI and AHI makes it tempting to use the ODI as a complete substitute of the AHI and therefore replace the PM recording with a sole pulse oximetry measurement. However, this cannot be recommended yet. The earlier mentioned recent randomized controlled trial on PSG versus PM as diagnostic tool for OSA showed equal outcomes for PSG and type III PM but not for PSG and only oximetry on all outcomes (although there might be some bias in these results caused by reduced confidence of the physician in the oximetry measurement outcomes) [14]. Another randomized controlled trial showed that general practitioners can implement treatment of (sleepy) OSA patients with the same outcome (reduction in ESS) as sleep specialists using a two-step (questionnaire and oximetry) screening strategy [17]. These results are promising but were performed using trained nurses (of which one had previous sleep medicine experience). Therefore, more (“real-life”) prospective studies on the use of the ODI as diagnostic modality to start treatment (and to investigate in which populations this is valid) are necessary. If these studies show that the ODI can be used to start treatment, this may be even initiated by the general practitioner in some cases, which will decrease the load of the sleep centers.

There are some limitations to the current study. The high correlation between ODI and AHI was to be expected as no arousals were measured during the PM recordings and a desaturation is part of the hypopnea definition. Additionally,

Table 3 Cross tabulation of ODI < 5 to predict AHI < 5 in the test set

	AHI ≥ 5	AHI < 5	Total
ODI ≥ 5	881	7	888
ODI < 5	21	223	244
Total	902	230	1132

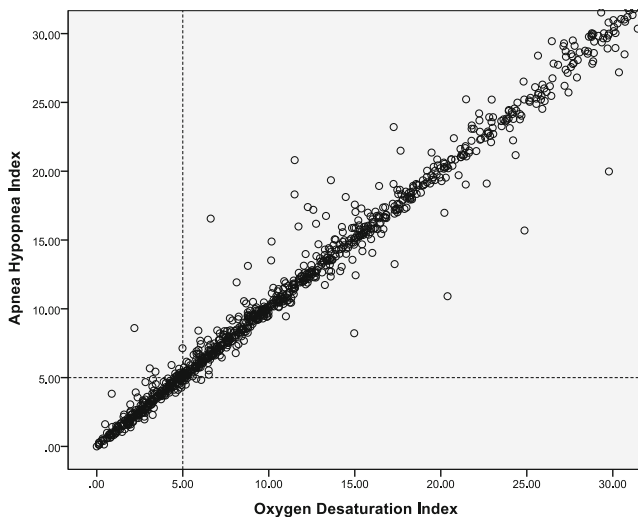


Fig. 1 Scatter plot of the ODI versus the AHI in the test set ($R^2 = 0.99$). The vertical dashed line indicates ODI = 5, and the horizontal dashed line indicates AHI = 5. In order to be able to assess the false negatives and false positives, the axes are limited to 30 events per hour for both the AHI and ODI

PSG indexes will always be more accurate and higher than indexes derived from limited sleep studies, where only recording time (with additional wake periods) is available and no arousal detection is possible. So PM and oximetry have the potential to underestimate OSA [9]. Therefore, in patients with a negative PM and marked symptoms (especially unexplained daytime sleepiness), a PSG should be performed [5]. This difference is reflected in the lower AUC found in other studies comparing ODI with PSG-derived AHI. Dawson et al. for instance found an AUC of 0.857 whereas Chung et al. found a AUC of 0.908 for the ODI in predicting $AHI \geq 5$ during a PSG recording [10, 18]. Also, in our study, the same time basis (visual corrected recording time) was used for calculation of the ODI and AHI. These factors might explain the somewhat lower correlations between ODI and AHI found in

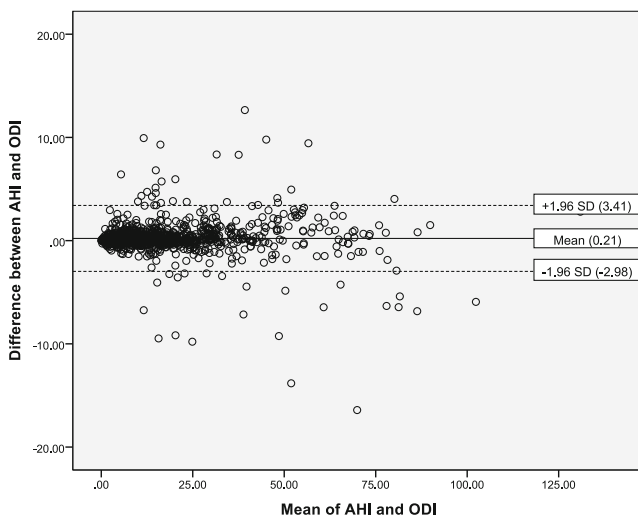


Fig. 2 Bland-Altman plot of the AHI versus the ODI in the test set

other studies on PSG data in which arousals can be measured and different time bases were applied [9, 10, 19].

It should be mentioned that pulse oximetry may be less reliable in dark skin type subjects [20], whereas the vast majority of our population consisted of light skin type subjects. Another explanation for the higher correlation in our data compared to previous data and especially the older publications might be the improvement in desaturation detection of the modern pulse oximeters. A short moving averaging time and a high data storage rate are now recommended [21, 22]. Furthermore, the type and location of the oximeter might influence the results. During this study, the same oximeter was used for calculation of the ODI and AHI. Using a different type of oximeter, e.g., an oximeter with a different sampling frequency or other filtering settings or applying the oximeter to another part of the body (such as the earlobe) might lower the resemblance between the AHI and ODI found in this study. Nevertheless, a recent study reported good agreement between the ODI as measured by finger transmission pulse oximetry (as done in the current presented data) and AHI measured by several signals including forehead reflectance oximetry [23]. Finally, wider use of the last AASM hypopnea definition with one defined decrease of flow (30%) and one defined depth of desaturation (3%) with or without an arousal will (by definition) increase the agreement with oximetry using a 3% desaturation definition [13]. As reported by Guilleminault and Reuhland, applying the two definitions of the AASM 2007 hypopnea definition and the so-called Chicago 1999 definition in the same patient group resulted in a more than 60% change in OSA detection. These studies formed the basis for the new sensitive hypopnea definition [13, 24, 25].

The ODI was measured simultaneously during the PM recordings. Although the saturation signal is assessed independently from the other signals, some bias may be present. A prospective validation study in which the correlation between ODI, derived from a sole pulse oximetry measurement, with AHI during PM recordings should therefore be performed. Another limitation is the population used in this study. The ultimate goal is to find an easy to use screening tool for OSA in a low prevalence population. The studied population however is a sleep center referral population with a high prevalence of OSA. Although the difference in prevalence might influence the negative predictive value, it will not influence the specificity. Furthermore, we expect no physiologic differences between our sleep center referral population and a more general screening population, which might influence the accuracy of pulse oximetry.

Concluding, an $ODI < 5$ predicts an $AHI < 5$ with high sensitivity and specificity when measured simultaneously using the same oximeter during PM recording. Similar to a negative PM recording, a negative oximetry should be followed by a PSG to rule out OSA completely.

Author's contributions TF contributed to the design, analysis of the data, interpretation of the data, and writing of the manuscript and takes full responsibility for the content of the manuscript, including the data and analysis; JB contributed to the design, data extraction, analysis of the data, and critical revision of the manuscript; LB contributed to the design, analysis of the data, and writing of the manuscript. JvdP contributed to the design, statistical analysis, interpretation of the data, and critical revision of the manuscript; FdJ contributed to the design, interpretation of the data, and critical revision of the manuscript; ME contributed to the design, data collection, interpretation of the data, and critical revision of the manuscript.

Compliance with ethical standards

Conflict of interest JB reports shares in DiagnOSAS B.V., a company that aims to facilitate screening for sleep apnea in a primary care setting. All other authors (TF, LB, JvdP, FdJ, and ME) certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge, or beliefs) in the subject matter or materials discussed in this manuscript.

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. Both the local ethics committee and the board of directors of the Medisch Spectrum Twente approved the study protocol.

Informed consent This study is based on anonymous data. Therefore, obtaining informed consent was deemed unnecessary (as approved by the local ethics committee).

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