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Correlations between home sleep apnea tests and polysomnography outcomes do not fully reflect the diagnostic accuracy of these tests

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DISCLOSURE STATEMENT

All authors have seen and approved the manuscript. Institution where work was performed: University of Oxford. Frederik Massie and Bart Van Pee are affiliated with Ectosense, the manufacturer of the NightOwl HSAT device. Jeroen Bergmann reports no conflicts of interest.

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ABSTRACT

Study Objectives: The clinical performance of home sleep apnea tests (HSATs) can be described by their (diagnostic) accuracy, defined as the percentage agreement with the obstructive sleep apnea severity category (normal, mild, moderate, and severe) based on polysomnography. Rather than reporting on accuracy, there has been a strong reliance in the literature to report correlation coefficients between the apnea-hypopnea index (AHI) of HSATs and polysomnography to support claims of diagnostic performance. This is surprising, as it has been well described that correlation coefficients are inadequate to evaluate equivalence between two parameters. The aim of this study was to systematically investigate the magnitude of the discrepancies between correlation coefficients and diagnostic accuracy reported in or retrievable from HSAT validation studies.

Methods: We compared the discrepancy between accuracy and AHI correlation coefficients of all validation papers that met the inclusion criteria. A total of 20 papers were retained, representing a participant pool of 1,652.

Results: The weighted average AHI correlation across all 20 papers was 0.82 and the weighted average accuracy was 0.61, highlighting a discrepancy of 0.21 and an overall misdiagnosis rate of 39%.

Conclusions: The results of our study confirm the need for increased scientific rigor in selecting primary performance endpoints to support HSATs' clinical performance claims.

Keywords: meta-analysis; accuracy; correlation; diagnosis; home sleep apnea testing

BRIEF SUMMARY

Current Knowledge/Study Rationale: Rather than reporting on diagnostic accuracy, there has been a strong reliance in the home sleep apnea testing (HSAT) literature on correlation coefficients between the apnea-hypopnea index (AHI) of HSATs and polysomnography as primary endpoint parameter to support claims of diagnostic performance. Nevertheless, it is known that correlation coefficients are inadequate to evaluate equivalence between two parameters. It was the aim of our study to systematically investigate the magnitude of the discrepancies between correlation coefficients and diagnostic accuracy reported in or retrievable from HSAT validation studies.

Study Impact: Our meta-analysis revealed a discrepancy of 21% between the AHI correlation and diagnostic accuracy. This highlights the need for increased scientific rigor in selecting performance endpoints to describe HSATs' performance.

INTRODUCTION

The American Academy of Sleep Medicine (AASM) clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea (OSA) in adults¹ defines the severity of OSA by whether the apnea-hypopnea index (AHI) is lower than 5 (normal), between 5 and 15 (mild OSA), between 15 and 30 (moderate OSA), or above 30 events per hour of sleep (severe OSA).

The performance of a home sleep apnea test (HSAT) can be evaluated by determining the percentage agreement of the OSA severity (normal, mild, moderate, or severe OSA) estimated by the HSAT with that determined by concurrently administered gold-standard polysomnography (PSG). This percentage agreement is commonly referred to as the (diagnostic) accuracy or the (diagnostic) concordance.

Yalamanchali et al² performed a comprehensive meta-analysis of the clinical performance of the most frequently deployed HSAT by systematically reviewing all papers which reported on the AHI correlation between the HSAT and PSG. From the apparently very strong correlation coefficients reported in the included papers, the authors concluded that the HSAT represents a viable alternative to PSG for confirmation of clinically suspected sleep apnea.

However, it has been well described in domains outside of sleep medicine that correlation coefficients such as Pearson's and Spearman's correlation are inadequate in describing the degree of one-on-one correspondence of two diagnostic endpoint parameters³. Almost two decades ago, Flemons et al^{4,5} pointed out very poignantly, based on an example comparing the RDI of HSAT and the AHI of PSG, how (Pearson) correlation coefficients are only able to indicate whether two measurements are (linearly) related, and not whether they have a similar magnitude.

Indeed, the Pearson correlation coefficient attains the maximum value of 1 upon a perfect linear relationship between two endpoint parameters, but it does not penalize a constant offset or scaling factor between the parameters. Worse in this context is the Spearman correlation coefficient, as it attains the maximum value of 1 when there is a perfect monotonously increasing relationship between the two parameters, without penalizing for non-linearity of such relationship. Correlation coefficients are also heavily influenced by extreme datapoints, such as very high AHIs.

These issues can be illustrated by the examples presented in **Figure 1**. All 4 subfigures show how AHI correlation coefficients can be arbitrarily high for devices with little to no clinical utility (as illustrated by diagnostic accuracies of less than 0.6). The top left and right subfigure respectively show how the Pearson correlation does not take scaling mismatches and constant offsets between the AHIs of HSAT and PSG into account. The bottom left figure shows how low AHIs (< 5) and extreme AHIs (>30) skew Pearson correlations to misleadingly large values, while the intrinsic diagnostic accuracy is very low. The bottom left figure has the same diagnostic accuracy of 0.5 as the bottom right but has fewer extreme AHI values in the sample pool, highlighting the collapse of the Pearson correlation in absence of extremity-introduced bias. Importantly, extremely low, and high AHIs, while excessively influencing correlations, have the least relevance in the performance evaluation of a HSAT. Indeed, it is comparatively straightforward to detect a near-complete absence of respiratory events (e.g., by a completely flat SpO₂ trace) or an extreme prevalence of respiratory events (e.g., by glancing the presence of extremely frequent oxygen desaturations). The patients most challenging to assess with any HSAT device are those with AHIs between 5 and 30, a range of particular importance for therapeutic decisions.

A recent study by Ioachimescu et al⁶ in which the HSAT device described by Yalamanchali et al² was evaluated against PSG on 500 participants, reported a very apparent discrepancy between the study's AHI's Pearson correlation of 0.80 and diagnostic accuracy of 0.53. These findings drove a starkly different conclusion than the one by Yalamanchali et al². Indeed, the authors stated that because of the large diagnostic misclassification rate, patients without OSA or mild disease assessed by the HSAT should undergo repeat in-laboratory PSG, as such limiting the device's utility to inclusion screening. These conflicting conclusions highlight the peril of reliance on correlation coefficients as opposed to diagnostic accuracy as primary clinical performance endpoint of HSAT devices.

Prompted by the scientific community's surprise⁷ about these findings, we systematically compared the discrepancy between diagnostic accuracy and AHI correlation coefficients of all published validation studies of the HSAT devices that met the search criteria.

METHODS

In order to allow for across-trial weighted-average aggregation of accuracy and correlation parameters, we limited the inclusion of HSAT types to the single most frequently validated HSAT device. The WatchPAT device (Itamar Medical, Israel) was found to be the most frequently included in clinical validation studies (approximately 20% of all HSAT validation studies report on this device).

As such, we searched PubMed on April 3rd 2021 for the search term “‘*watchpat*’ or ‘*watch-pat*’ or ‘*watch pat*’”.

Any paper that met at least one of the exclusion criteria was discarded from further analysis. The following exclusion criteria were used:

1. The paper was not available in the English language
2. The paper did not report on the performance validation of the HSAT device
3. The HSAT was not concurrently administered with the PSG
4. No diagnostic accuracy could be retrieved from the paper
5. No AHI correlation coefficient could be retrieved from the paper

For all included papers, the correlation between the (automated) AHI estimate of HSAT and PSG was retrieved. We additionally registered the type of the reported correlation coefficient (Spearman, Pearson, or Intraclass-correlation coefficient, ICC). For all included papers, we retrieved the accuracy of the HSAT. For papers for which the accuracy was not explicitly reported, or for which it could not be precisely calculated from the confusion matrix, we estimated the accuracy based on the datapoints of the scatter plots or the Bland-Altman plots, or inverse-calculated the accuracy from the disease prevalence, sensitivity and specificity values. Such scatter plots are equivalent to those presented in **Figure 1**. We counted the number of dots falling in the green rectangles and divided this number by the total number of dots to arrive at the accuracy value. Any discrepancy between the estimated participant size from the scatter plots or Bland-Altman plots and the reported participant size was also identified.

As accuracy estimates could be impacted by incomplete or incorrect visual retrieval of the datapoints, we performed a subgroup analysis for which papers that did not allow exact diagnostic accuracy retrieval were excluded.

For papers for which only a respiratory disturbance index (RDI) correlation and accuracy could be retrieved, we used the RDI instead of the AHI. Finally, the scoring rules used to score the AHI by PSG were noted for each paper. We performed a subgroup analysis on papers that reported on the current (2012) AASM respiratory event scoring rules⁸.

We charted out the diagnostic accuracy and the AHI correlation coefficient for each included paper, ranked by decreasing study participant number. Finally, we calculated the overall (sample-size weighted average) accuracy and the AHI correlation coefficient of the total participant pool.

RESULTS

As illustrated in **Figure 2**, the search term resulted in the identification of 86 papers, of which 20 were retained after application of the exclusion criteria. 50 out of 86 identified papers were not considered HSAT validation studies, rendering this the main reason for exclusion.

The results of the systematic analysis are summarized in **Figure 3** and **Table 1**.

The weighted average AHI correlation across all 20 papers was 0.82 and the weighted average accuracy was 0.61, highlighting a discrepancy of 0.21. The lowest observed accuracy was 0.35

(correlation 0.76) and the highest observed accuracy was 0.95 (correlation 0.95), which illustrates a large degree of performance variation between studies. The lowest observed AHI correlation was 0.65 (accuracy 0.61) and the highest observed AHI correlation was 0.96 (accuracy 0.74).

The weighted average AHI correlation and accuracy across all papers for which the accuracy could exactly be retrieved were respectively 0.82 and 0.58. For 6 out of 20 papers the accuracy was exactly retrievable. 6 out of 20 studies reported on the AASM 2012 scoring rules using the 1A rule for hypopnea requiring 3% desaturations. Only one study reported (partially) on the on the AASM 2012 scoring rules using the 1B rule for hypopnea requiring 4% desaturations. Comparing the studies that scored using any of the AASM 2012 rules to the papers which applied an older scoring rule revealed a difference of 0.04 (to 0.59 to 0.63) for the accuracy and 0.07 (0.79 to 0.87) where the highest number was found for the older rules.

DISCUSSION

Similar to the results reported by Ioachimescu et al⁶, our meta-analysis determined a discrepancy of 21% between the diagnostic accuracy of 61% and correlation coefficient of 82%, derived from a total participant pool size of 1,652. When only considering papers reporting on the latest AASM scoring rules, a misdiagnosis rate of 41% was found. For only 6 out of the 20 included papers, the diagnostic accuracy could directly be retrieved or exactly calculated, revealing a large underreporting of this important endpoint parameter.

These observations confirm the urgent need for researchers and device manufacturers to increase scientific rigor and transparency in the presentation of HSAT devices' clinical performance by complementing their reporting with diagnostic accuracy, in a move away from the over-reliance on correlations. This study can be viewed as a precursor to much needed future work on the determination of a statistically robust set of parameters to characterize the performance of HSATs in general, and the agreement between HSAT and PSG in particular. This problem is embedded within the broader observation that hypothesis testing is typically being deployed for the determination of significant differences between two measurements, and not for the determination of their equivalence. This meta-analysis had several limitations. Firstly, the accuracy had to be estimated from alternative data such as scatter plots and Bland-Altman plots for 16 out of 20 papers, due to lack of explicit reporting of the parameter. Secondly, only 6 papers reported on the latest 2012 AASM scoring rules and only one paper reported on the latest 1B rules for the scoring of hypopnea. Finally, there was heterogeneity in participant population characteristics. Most papers (11/20) reported on a participant population with a high suspicion of OSA, while other papers discussed specific participant populations such as those with cardiovascular or pulmonary comorbidities. Nevertheless, the totality of participants represents a patient group that closely aligns with the HSAT's utilization in the market.

ABBREVIATIONS

AASM	American Academy of Sleep Medicine
AHI	apnea-hypopnea index
HSAT	home sleep apnea test
ICC	intraclass-correlation coefficient
OSA	obstructive sleep apnea
PSG	polysomnography
RDI	respiratory disturbance index

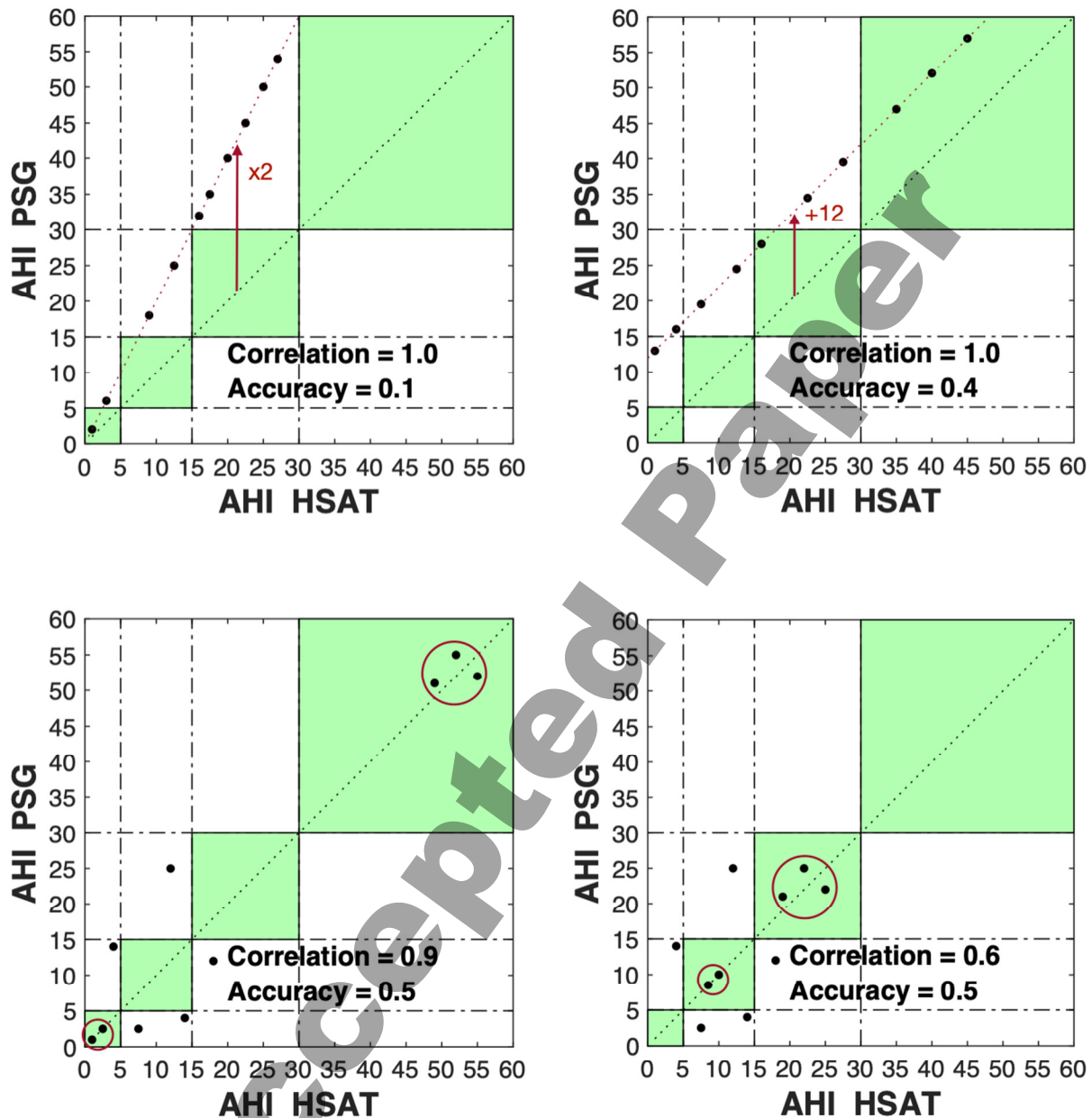
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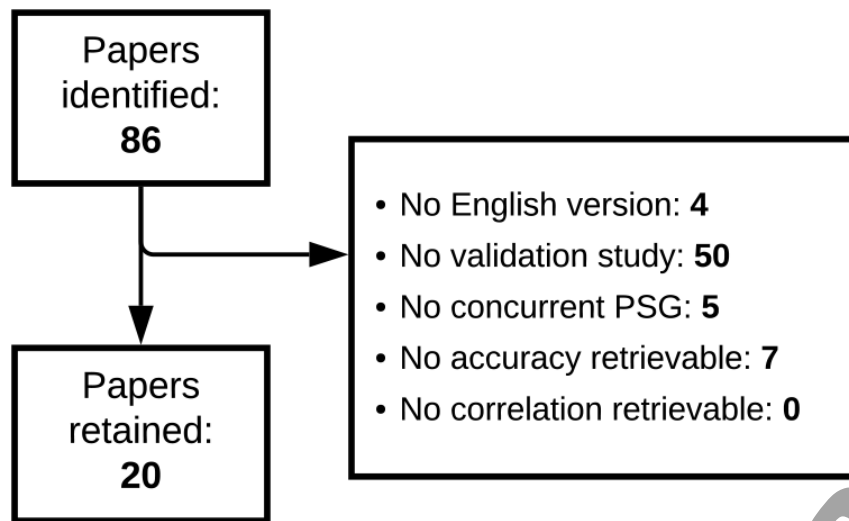
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Figure 1—Toy example scatterplots highlighting issues of relying on correlation coefficients to describe equivalence between two parameters.



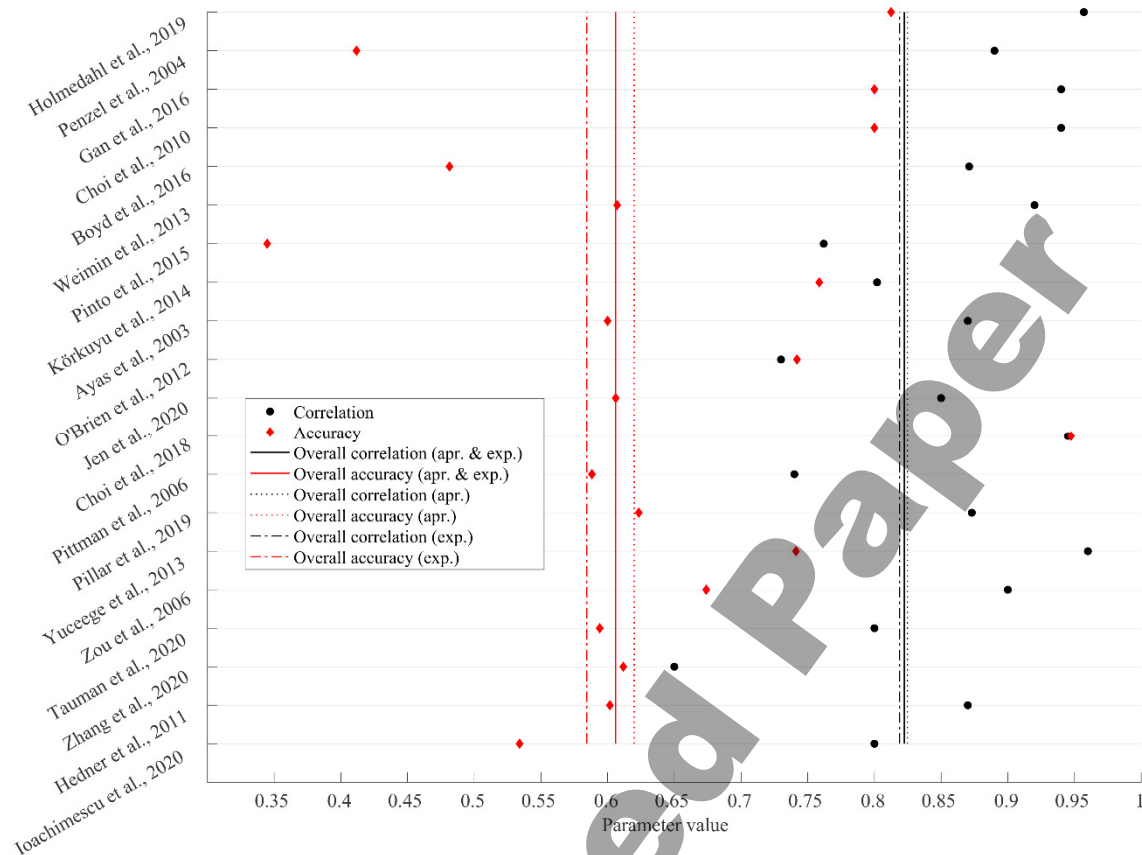
The green shaded rectangles mark the areas in which PSG and HSAT agree on the AHI severity category. Top Left: AHIs differ by a constant scaling factor ($\text{AHI PSG} = 2 \times \text{AHI HSAT}$). Top Right: AHIs differ by a constant offset ($\text{AHI PSG} = \text{AHI HSAT} + 12$). The differences between AHI PSG and AHI HSAT do not impact the correlation coefficient but strongly impact the accuracy. Bottom: Extreme values disproportionately influence correlation coefficients. Moving extreme values (dots within red circles) more to the center of the spectrum, without altering the accuracy, has a strong effect on the correlation coefficient. This is observed by comparing the Bottom Left (correlation = 0.9) and Bottom Right (correlation = 0.6) subfigures. AHI = apnea-hypopnea index, HSAT = home sleep apnea test, PSG = polysomnography.

Figure 2—Overview of identified and retained papers and the reasons for any exclusions.



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Figure 3—Comparison of accuracy and correlations for each included paper.



Comparison of accuracy and AHI correlations (horizontal axis) as retrieved from each included paper (vertical axis). Papers are ranked by increasing sample size (largest at bottom). Overall accuracy and correlation were calculated from a weighted average of all individual trials, with the weights equal to the trial population size. AHI = apnea-hypopnea index, apr. = accuracy was approximated from the graphs or inverse-calculated, ex. = accuracy was exactly inferred.

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Table 1—Tabulation of accuracy and correlations for each included paper.

Study	AHI or RDI	Correlation (type)	Accuracy (apr. or exp.)	Difference	N (reported)	Scoring rules
Holmedahl et al, 2019	AHI	0.96 (ICC)	0.81 (apr.)	0.15	16	O
Penzel et al, 2004	RDI	0.89 (Pearson)	0.41 (apr.)	0.48	17	O
Gan et al, 2016	AHI	0.94 (Pearson)	0.80 (apr.)	0.14	20	A
Choi et al, 2010	AHI	0.94 (Pearson)	0.80 (exp.)	0.14	25	O
Boyd et al, 2016	AHI	0.87 (Pearson)	0.48 (apr.)	0.39	27 (28)	O
Weimin et al, 2013	AHI	0.92 (Pearson)	0.61 (exp.)	0.31	28	O
Pinto et al, 2015	AHI	0.76 (Spearman)	0.35 (apr.)	0.42	29 (30)	O
Körkuyu et al, 2014	AHI	0.80 (Spearman)	0.76 (apr.)	0.04	29 (30)	O
Ayas et al, 2003	AHI	0.87 (Pearson)	0.60 (exp.)	0.27	30	O
O'Brien et al, 2012	AHI	0.73 (Pearson)	0.74 (exp.)	-0.01	31	O
Jen et al, 2020	AHI	0.85 (Pearson)	0.61 (apr.)	0.24	33	O
Choi et al, 2018	AHI	0.95 (Spearman)	0.95 (exp.)	0.00	38	A
Pittman et al, 2006	AHI	0.74 (ICC)	0.59 (apr.)	0.15	68 (70)	O
Pillar et al, 2019	AHI	0.87 (Pearson)	0.62 (apr.)	0.25	77 (84)	A
Yuceegee et al, 2013	AHI	0.96 (Pearson)	0.74 (apr.)	0.22	85	O
Zou et al, 2006	AHI	0.90 (Pearson)	0.67 (apr.)	0.23	92	O
Tauman et al, 2020	AHI	0.80 (Pearson)	0.59 (apr.)	0.21	101	A
Zhang et al, 2020	AHI	0.65 (Spearman)	0.61 (apr.)	0.04	170	A
Hedner et al, 2011	RDI	0.87 (ICC)	0.60 (apr.)	0.27	236	O
Ioachimescu et al, 2020	AHI	0.80 (Pearson)	0.53 (exp.)	0.27	500	A and B
Overall (A or B)	AHI	0.79	0.59	0.20	906	A or B
Overall (O)	AHI or RDI	0.87	0.63	0.24	746	O
Overall (apr.)	AHI or RDI	0.83	0.62 (apr.)	0.21	1000	A, B or O
Overall (exp.)	AHI or RDI	0.82	0.58 (exp.)	0.24	652	A, B or O
Overall	AHI or RDI	0.82	0.61	0.21	1652	A, B or O

Papers are ranked by decreasing sample size. Papers exclusively reporting on the RDI were highlighted as such in column 2. For “apr.” papers, the participant number (N) is displayed based on the paper’s graphs, with the reported number between brackets when it was different compared to the overall reported sample size. A = AASM 2012 scoring rules with 1A rule for hypopnea. B = AASM 2012 scoring rules with 1B rule for hypopnea. O = scoring rule other than any AASM 2012 rule. “Overall (A or B)” and “Overall (O)” respectively contains the sample-size weighted average of all studies scored by “A or B” rules or “O” rules. “Overall (apr.)” and “Overall (exp.)” respectively contains the sample-size weighted average of all studies with an “apr” or “exp” accuracy. AHI = apnea-hypopnea index, apr. = accuracy was approximated from the graphs or inverse-calculated, exp. = accuracy was exactly inferred, ICC = intraclass correlation coefficient, N = participant number, RDI = respiratory disturbance index.