Number of Nights to Achieve High Sensitivity/ Specificity for Detecting OSA Using a Large US Sample by Home Under-Mattress Devices

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Introduction

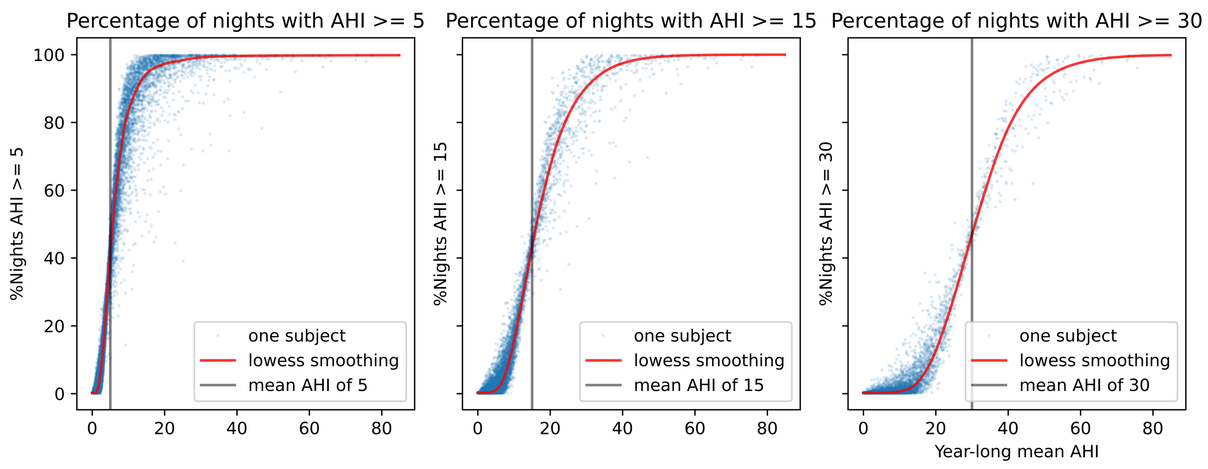
Clinical sleep studies typically rely on one night for OSA detection and diagnosis. However, uncertainty exists regarding the degree of AHI stability across different nights. Population studies collecting continuous nightly data on a large scale enable detection of night-to-night variability in OSA severity; this study is the largest to date for evaluation of the number of nights to achieve high sensitivity/specificity for OSA detection.

Methods

Sleep-disordered breathing was analyzed by a commercially available home monitoring device (Sleeptracker-AI® Monitor, Fullpower Technologies Inc., California, USA). The device passively monitors sleep using piezoelectric sensors. Validated sleep and respiratory parameters were derived from device data. The de-identified data were analyzed, following review and exemption of the study (#57681) from Stanford University IRB. Data from 10/01/2021 to 09/30/2022 were reviewed in 96,228 individuals with 19,148,323 recorded nights. Individuals with at least 300 nights with a computed AHI (TST≥4hrs) were included in the analytic dataset.

Met Inclusion Criteria	
23,105 Participants 7,947,840 Recorded Nights	10,711 Men, 49.6±12.93 years 9,430 Women, 49.4±12.85 years 2,964 Unspecified Gender, 50.4±14.37 years

Results: Percentage of Nights

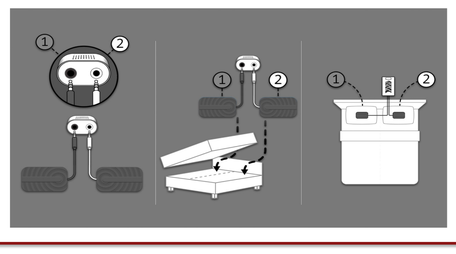


Results: Off-By-Two-Categories Errors

For moderate-to-severe and severe OSA subjects over 1 year, means of 5.1 ± 7.7% and 5.4 ± 7.3% nights, respectively, showed OSA severity decreases by 2+ categories (i.e., moderate to normal, severe to mild/normal):

OSA Category from Year-Long Mean AHI	Fraction of Nights (Mean ± SD) with AHI Off by 2 OSA Categories
None	0.2 ± 0.7%
Mild	0.9 ± 1.9%
Moderate	5.1 ± 7.7%
Severe	5.4 ± 7.3%

Device Setup



Results: Sensitivity & Specificity

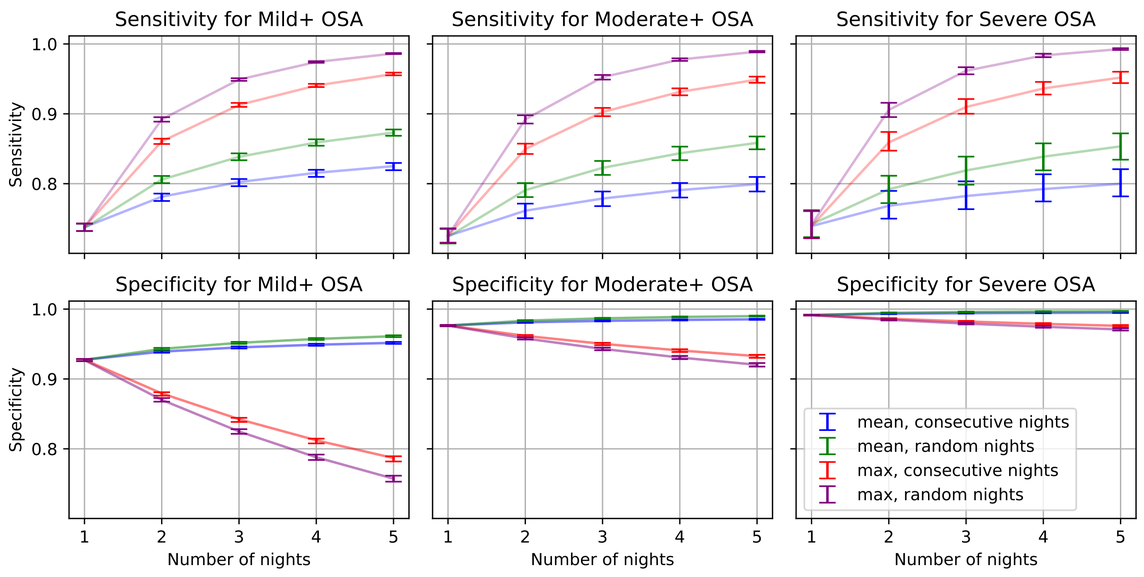
Maximum (but not mean) AHIs for each individual for randomly-selected (vs. consecutive) nights revealed the following sensitivities (≥95%) and specificities [and bootstrapped CIs] for detecting any, moderate-to-severe, and severe OSA, respectively, as categorized by mean AHI over 1 year:

#Nights* N	Sensitivity & Specificity of Max AHI of N Nights* vs OSA Category from Year-Long Mean AHI		
	Mild+	Moderate+	Severe
1	73.8% [73.3,74.2] 92.7% [92.6,92.8]	72.6% [71.7,73.4] 97.6% [97.6,97.7]	74.2% [72.5,75.8] 99.1% [99.1,99.2]
2	89.2% [88.9,89.5] 87.0% [86.8,87.2]	89.2% [88.7,89.7] 95.8% [95.7,95.9]	90.6% [89.7,91.4] 98.5% [98.4,98.5]
3	94.9% [94.8,95.1] 82.5% [82.2,82.7]	95.2% [95.0,95.5] 94.3% [94.1,94.5]	96.2% [95.8,96.6] 97.9% [97.8,98.0]
4	97.4% [97.3,97.5] 78.8% [78.5,79.1]	97.8% [97.6,97.9] 93.1% [92.9,93.3]	98.4% [98.1,98.6] 97.5% [97.4,97.6]
5	98.6% [98.6,98.7] 75.7% [75.4,76.1]	98.9% [98.8,99.0] 92.0% [91.8,92.2]	99.3% [99.2,99.4] 97.1% [97.0,97.2]

Number of randomly selected nights from which the maximum AHI was obtained

Sensitivities for a single night were in the low 70s, and, for maximum AHI over two randomly-selected nights, near 90%, with a tradeoff for decreased specificities for 3+ nights.

Mean AHI across nights suffers from low sensitivity even at 5 randomly selected nights, with sensitivities 85.8% for Moderate+ detection and 85.3% for Severe detection.



Conclusions

Use of a noninvasive in-home monitoring device enabling collection and analysis of a large sample of sleep/respiratory data on a continuous nightly basis showed that a single night yields low sensitivity for detection of OSA and on average OSA severity decreased by 2 categories on 5% or more nights.

Maximum (but not mean) AHI across 3 non-consecutive nights yields good sensitivities/specificities for moderate-to-severe and severe OSA detection. This supports OSA diagnosis involving multiple, non-consecutive nights, and the use of the most severe finding on up to 3 nights.

Ongoing work explores statistics for nights beyond 3 to further improve sensitivity/specificity.

References

Ding F, Cotton-Clay A, Fava L, Easwar V, Kinsolving A, Kahn P, Rama A, Kushida C. Polysomnographic validation of an under-mattress monitoring device in estimating sleep architecture and obstructive sleep apnea in adults. Sleep Medicine 2022 Aug 1;96:20-7. doi: 10.1016/j.sleep.2022.04.010. PMID: 35576830.