

Operational Impact of AI-derived AHI on Inconclusive HSAT studies: sex specific reclassification in 3094 home tests

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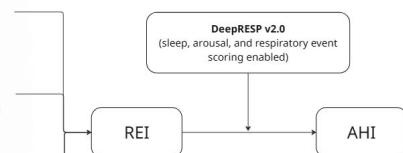
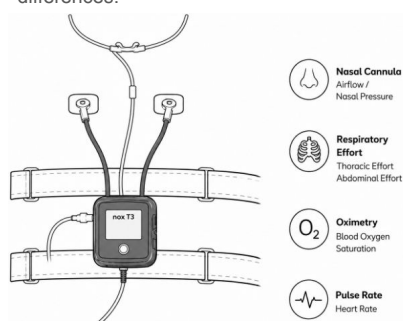
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Introduction

Home sleep apnea testing (HSAT) typically reports a respiratory event index (REI, events/hour of monitoring) rather than apnea-hypopnea index (AHI, events/hour of sleep). REI underestimates disease severity, particularly for arousal-based hypopneas common in women, leaving symptomatic patients with inconclusive results (REI<5) that prompt repeat testing or loss to follow-up. We evaluated how an FDA-cleared AI system that derives AHI from HSAT signals changes HSAT classification, with emphasis on sex differences.



REI Classification	AHI Classification
< 5	< 5
5 - 14.9	5 - 14.9
15 - 29.9	15 - 29.9
30 +	30 +

Methods

We retrospectively analyzed 3094 adult HSATs (1785 men; 1147 women) from a single sleep center. REI came from routine clinical processing. AHI was computed from the same signals by DeepRESP v2.0 (K252330), an FDA-cleared SaMD for sleep staging, arousal detection, and respiratory scoring. REI and AHI were categorized as <5, 5–14.9, 15–29.9, and ≥30 events/hour. We cross-tabulated REI versus AHI overall and by sex, focusing on reclassification of REI<5 and REI<15 relative to AHI-defined moderate–severe disease.

Figure 1.

The standard type III sleep recording, or home sleep apnea testing (HSAT) is missing the signals usually required to score sleep stages and arousals. This results in underestimation of the obtained respiratory event index (REI) with regards to disease severity. By using the DeepRESP v2.0, an AHI can be obtained from HSAT signals, resulting in changes in the severity classification.

Results

Changes Overall

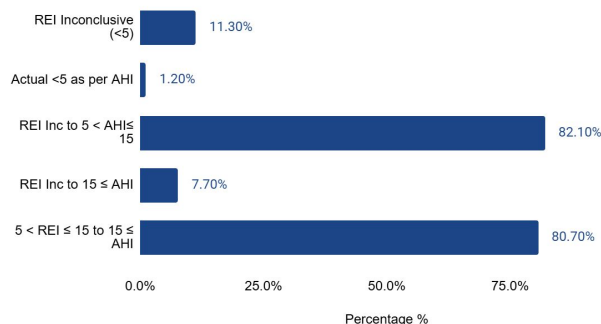


Figure 2. In the overall dataset, 11.3% were classified as inconclusive based on the REI value. This number was reduced to 1.20% based on the AHI value obtained using DeepRESP. Out of the original inconclusive studies, 82.1% were reclassified to have mild OSA, and 7.7% were reclassified to have either moderate or severe OSA. Out of the total number of analysed studies that received a Mild classification using the REI, 80.7% were reclassified as either Moderate or Severe OSA using the obtained AHI

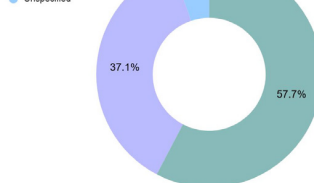
By REI, 351/3094 studies (11.3%) were <5, including 122/1785 men (6.8%) and 205/1147 women (17.9%); with AI-derived AHI, only 36/351 (10.3%) remained <5. Reclassification from REI<5 to AHI≥5 occurred in 113 men (6.3% of all men) and 178 women (15.5% of all women), so nearly one in six women had an REI-negative HSAT that became AHI-positive. Among patients with AHI≥15, 727/2374 (30.6%) had REI<15, affecting 27.4% of men (411/1499) and 37.4% of women (283/756).

Conclusions

AI-derived AHI converted most REI-negative HSATs into positive or higher-severity studies, and women with REI values just below diagnostic thresholds were more often moved into higher severity categories. These findings suggest that REI alone disproportionately underestimates disease burden in women, whereas automated AHI reduces inconclusive HSATs and may streamline diagnostic pathways; effects on repeat testing and treatment require prospective evaluation.

A

Dataset split by sex



B

Changes by Gender

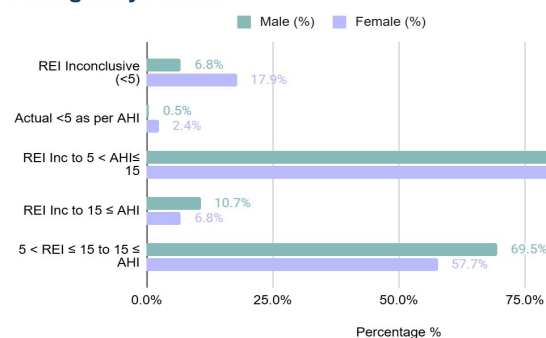


Figure 3A: Out of 3094 sleep recordings, 37.1% were from females. Figure 3B: In the overall dataset 6.8% of males and 17.9% of females were classified as inconclusive based on the REI value. This number was reduced to 0.5% for males, and 2.4% for females based on the AHI value obtained using DeepRESP. Out of the original inconclusive studies, 84% of the males and 80.5% of the females were reclassified as having either moderate or severe OSA. Additionally, for those studies that were originally classified as having Mild OSA based on the REI, 69.5% of the males and 57.7% of the females were reclassified as having either moderate or severe OSA when based on the AHI.

Support

Internal quality-improvement project funded by Nox Health. These operational data were not part of the device's 510(k) submission and are investigational, not intended to represent official device performance, support promotional claims, or modify labeling.