

# **A Limited-Channel Single-Site System to Diagnose Obstructive Sleep Apnea (OSA): Comparison of Full Polysomnography (PSG) with In-home and In-Lab Recordings**

*Westbrook P,<sup>1</sup> Levendowski D,<sup>1</sup> Zavora T,<sup>1</sup> Dalati R,<sup>1</sup> Cvetinovic M,<sup>1</sup> Popovic M,<sup>2</sup> Velimirovic V,<sup>1</sup> Simeunovic V,<sup>1</sup> Dimitrijevic A,<sup>1</sup> Henninger D,<sup>3</sup>*

(1) Advanced Brain Monitoring, Inc., Carlsbad, CA, (2) University of Belgrade, Serbia and Montenegro, (3) Murrieta Sleep Medical Clinic, Murrieta, CA

## **Introduction:**

An apnea risk evaluation system (ARES) was evaluated during both laboratory and in-home use. The ARES uses a multivariate approach that integrates: a self-applied, single-site (forehead) device to acquire continuous full-disclosure physiological signals (i.e., forehead pulse-oximetry (SpO<sub>2</sub>), pulse rate, snoring sounds, head movement and head position); a validated questionnaire based on anthropomorphic and clinical information; automated software to recognize and quantify abnormal respiratory events; and an expert system which utilizes this information to identify levels of severity.

## **Methods:**

Laboratory-PSG and simultaneous ARES recordings were acquired from 198 subjects. Subjects wore the ARES in-home for two nights prior or subsequent to their PSG (based on random assignment). Fifteen patient records were dropped; seven due to study length (minimum: lab  $\geq$ 1.5-hours, in-home  $\geq$ 6-hours), eight due to poor quality data (PSG=6, ARES=2), leaving 173 records for analysis. The population included 129 patients referred for PSG, and 16 subjects classified as at-risk and 28 no-risk based on the ARES-questionnaire analysis.

The PSG Apnea-Hypopnea Index (PSG-AHI) was based on AASM guidelines for detection of obstructive and central apneas/hypopneas, modified to require a minimum 3% rather than a 4% SpO<sub>2</sub> desaturation. A diagnostic cut-off of AHI=10 was used to establish the accuracy and validity of the ARES.

Calculation of the ARES respiratory disturbance index (ARES-RDI) was based on minimum SpO<sub>2</sub> desaturation and resaturation requirements that varied depending on the SpO<sub>2</sub> level at the point of maximum saturation, (e.g.,  $\geq$ 93.0%=2.5%-2.5%, 92.9%-91.5%=3.0%-2.7%, 91.4-88%=3.5%-3.0%, <88%=4.0%-3.2%) with moderate vs. severe obstructive events determined by the slope of resaturation. When maximum saturations were  $\geq$ 95%, events with 2.2% desaturation and resaturation were included if accompanied by head movement and/or heart rate arousals.

## **Results:**

The PSG-AHI was significantly correlated with both in-lab ARES-RDI ( $r=0.96$ ) and in-home ARES-RDI ( $r=0.88$ ). The best-fit line for the lab results ( $y=3.9+0.92x$ ) showed the ARES-RDI consistently greater across all PSG-AHI ranges (0-117 events/hour). The best-fit line for the in-home results ( $y=6.2+0.70x$ ) showed the ARES-RDI greater until PSG-AHI=27 and then lower. Bland-Altman plots show a tight distribution of the differences between the ARES-RDI and PSG-AHI plotted around the mean (AHI+RDI/2) for both lab (mean= $1.7 \pm 7.1$  events/hour) and in-home (mean= $-2.3 \pm 14.5$  events/hour) results.

The sensitivity and specificity for the lab-ARES, compared to PSG with a diagnostic cut-off of 10, was 96% and 86%. The negative and positive predictive values were 92% and 94%.

For the in-home ARES, the sensitivity and specificity was 91% and 85%. The negative and positive predictive values were 91% and 85%. Five of the 10 false-positive in-home ARES results were classified as false-positives by the lab-ARES. Of the 10 false-negative in-home ARES, seven were identified as "at-risk" by the ARES questionnaire analysis.

## **Conclusions:**

The ARES demonstrated consistently high specificity for both lab and in-home recordings. The in-home sensitivity was slightly lower than in the lab, and may be explained in-home vs in-lab variability. In

persons with possible OSA who a priori do not require an attended study, the ARES could be part of a low-cost alternative-management strategy.

This work was supported by NIH NHLBI grant number HL66829. The authors Westbrook, Levendowski, Zavora, Cvetinovic are shareholders in Advanced Brain Monitoring, Inc.