

Determining the Accuracy of Sleep and Activity Patterns in Patients Undergoing Long-Term Ambulatory ECG Monitoring

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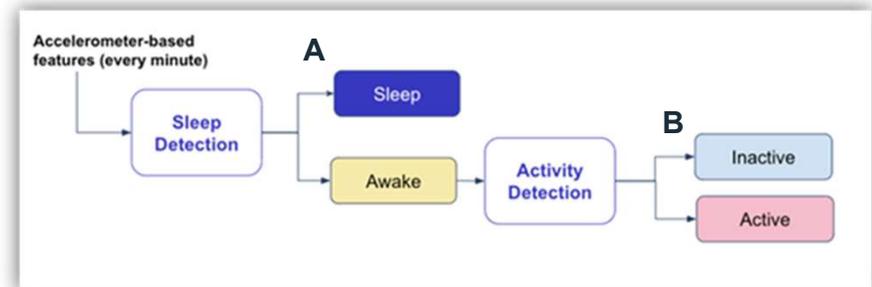
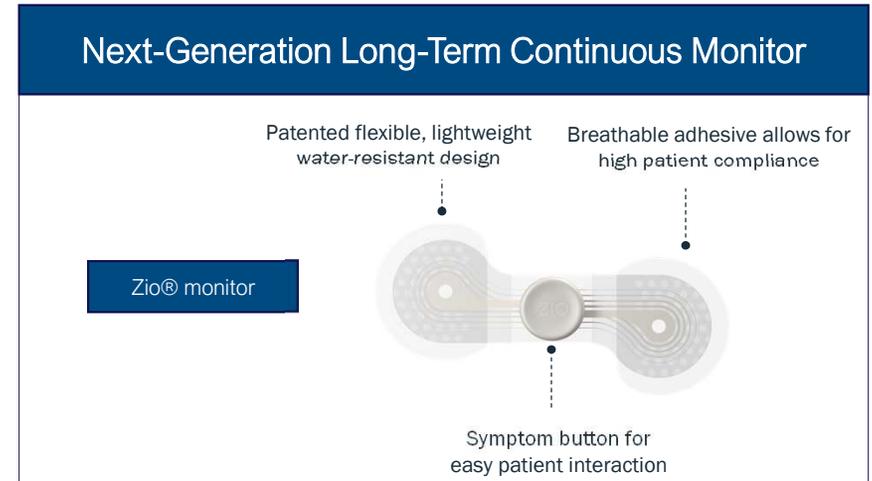
DISCLOSURES

- Mintu Turakhia is an employee and corporate officer of iRhythm Technologies. In the last 36 months, he has had research support from VA, NIH, AHA, Apple, Bristol Myers Squibbs, Bayer, Sanofi, and Gilead. He has equity in Connect America, Forward, Evidently, AliveCor, Hippocratic.AI, RCE Medical, PocketRN, and iRhythm
- Elaine Yu, Ardit Kacorri, Yuriko Tamura, Anthony Battisti, Vladimir Fokin, Evangelos Hytopoulos, Andrew Gilbert, and Charlotte Bame, are employees of iRhythm Technologies, Inc.
- R Bogan, V Mysliwec, M Miller: Research support from iRhythm Technologies for the conduct of the iSLEEP - ZZZio! Study
- Disclaimer: Accelerometer data and the sleep and activity classification algorithm are research data and not available for any commercial use

AIMS

AECG-based Sleep and Activity Detection

- Ambulatory ECG (AECG) enables heart rhythm monitoring during daily activities with focus on arrhythmia detection
- Detection and quantification of sleep and activity patterns during monitoring may provide lifestyle insights and context to arrhythmia findings
- An AI algorithm was developed to classify sleep, activity, and inactivity using a novel AECG patch with embedded accelerometry (Zio monitor; iRhythm Technologies, San Francisco, CA)
- We sought to evaluate algorithm performance vs. FDA-cleared actigraphy and consumer devices



Two-step approach for classification of Sleep and Activity Data:

- A) Sleep detection classifies all epochs as either Sleep or Awake
- B) Awake state is further classified as either Active or Inactive

METHODS

Data Acquisition

Clinical Study Overview

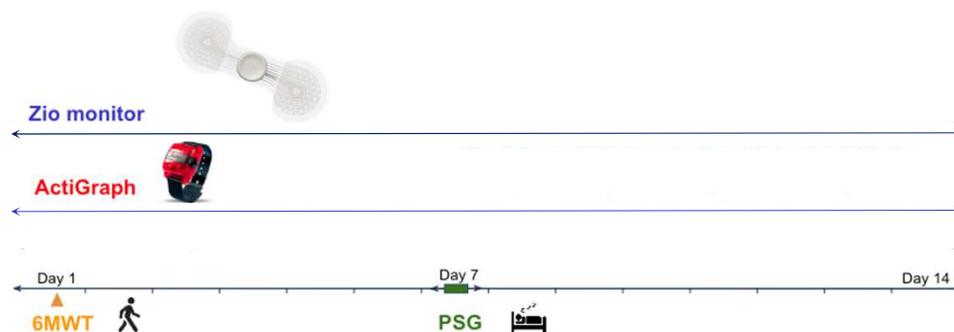
- Prospective clinical study enrolled participants across four AASM-qualified sleep centers to support algorithm training and validation
- Treatment for sleep disordered breathing was excluded

Participant Requirements

- FDA-cleared Zio[®] monitor AECG patch and FDA-cleared actigraphy reference (wGT3X, Actigraph; Pensacola, FL) worn simultaneously for 14 days
- 6-minute walk test at start of device wear
- Overnight, in-clinic polysomnography (PSG) at 7±3 days following AECG application

Reference Data

- Registered Polysomnographic Technologists classified PSG data as sleep or wake (in 1-minute epochs) per AASM standards
- Epochs classified as activity (≥ 2.8 metabolic equivalents of task or METs) or inactivity (< 2.8 METs) obtained from actigraphy reference
- AECG Sleep and Activity algorithms trained and validated using PSG and actigraphy reference labels



Data Acquisition:

- Zio monitor and actigraphy reference device worn simultaneously for 14 days
- 6-minute walk test performed upon device application on day 1
- Overnight, in-clinic PSG testing occurred at 7 ± 3 days

METHODS

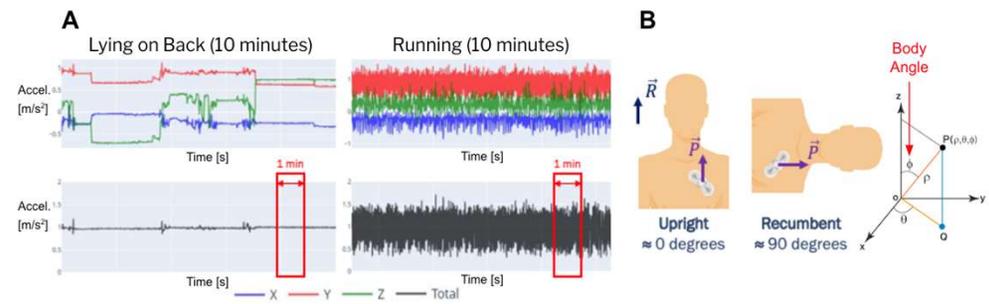
Algorithm Development and Validation

Model Development and Training

- Data were divided 1:1 into training and validation sets
- Five-fold cross validation of training set was employed for feature and model selection
- Total activity and body angle were selected as predominant feature classes due to their ability to delineate sleep / wake
- Final support vector machine (SVM) model was trained on selected features using the entire training set

Algorithm Performance Assessment (Validation set)

- Sleep (PSG): Per-minute sensitivity and specificity of the Sleep algorithm evaluated vs. PSG reference
- Sleep (24-hr): Sleep performance also assessed vs. 24-hour reference (all PSG-labeled epochs + wake-labeled epochs sampled from the actigraphy reference)
- Activity: Per-minute sensitivity and specificity of the Activity algorithm evaluated vs. actigraphy reference, including 8 x 1-minute epochs sampled from walk test (4 min.) and PSG wake periods (4 min.)



Predominant Feature Classes:

- Standard deviation of total acceleration used to distinguish between periods of stillness and activity
- Body angle ranges from 0 to 90 degrees, with 0 as upright and 90 as recumbent

RESULTS

Population and Algorithm Performance

Enrolled Population

- 92 participants were enrolled: 57% female, 36% non-white, with mean age of 43±14 yrs.

Analysis Population

- Complete reference data available for 81/92 subjects used in training (n=40) or validation (n=41)
- Avg. sleep time = 5.9 hrs., avg. wake time = 1.2 hrs. for validation set during overnight PSG

Algorithm Performance

- Activity: Sens. = 97.0%, Spec. = 100% vs. actigraphy reference
- Sleep: Sens. = 88.8%, Spec. = 54.0% vs. PSG reference
- Sleep: Sens. = 88.8%, Spec. = 95.6% vs. 24-hr reference
- Performance of prior FDA-cleared actigraphy and consumer devices vs. PSG reference in classification of sleep¹:
 - 93-99% per-minute sens., 39-54% per-minute spec.

Participant Demographics for Training and Validation Sets

Participant Data	Training (N=40)	Validation (N=41)
Age (Mean±SD), years	44.0 ± 14.3	42.0 ± 13.0
Female, n (%)	18 (45.0%)	26 (63.4%)
BMI	29.3 ± 6.0	29.6 ± 5.3
Race, n (%)	White: 29 (72.5%) Black: 8 (20.0%) Asian: 1 (2.5%) American Indian: 1 (2.5%) Other: 1 (2.5%) Not Disclosed: 0 (0%)	White: 25 (61.0%) Black: 11 (26.8%) Asian: 0 (0%) American Indian: 2 (4.9%) Other: 2 (4.9%) Not Disclosed: 1 (2.4%)
Ethnicity, n (%)	Hispanic or Latino: 2 (5.0%) Not Hispanic or Latino: 38 (95.0%) Not Reported: 0 (0%)	Hispanic or Latino: 17 (41.5%) Not Hispanic or Latino: 23 (56.1%) Not Reported: 1 (2.4%)

Performance of the Sleep Algorithm Measured Against PSG-Only Reference and 24-Hour (PSG + Actigraphy) Reference

	Performance	All Epochs (Per-minute Level)	Per Subject Mean±SD
Reference Device: PSG during overnight sleep test (n=17,570 epochs)	Sensitivity	88.8%	89.2% ± 13.8%
	Specificity	54.0%	59.2% ± 23.7%
	Accuracy	83.0%	83.0% ± 13.0%
	PPV	90.6%	90.2% ± 11.4%
	NPV	49.3%	57.0% ± 25.2%
Reference Device: PSG + Actigraphy-wake over 24 hours (n=58,877 epochs)	Sensitivity	88.8%	89.2% ± 13.8%
	Specificity	95.6%	95.7% ± 3.3%
	Accuracy	93.9%	93.9% ± 4.0%
	PPV	87.0%	86.7% ± 11.5%
	NPV	96.3%	96.5% ± 4.3%

CONCLUSIONS

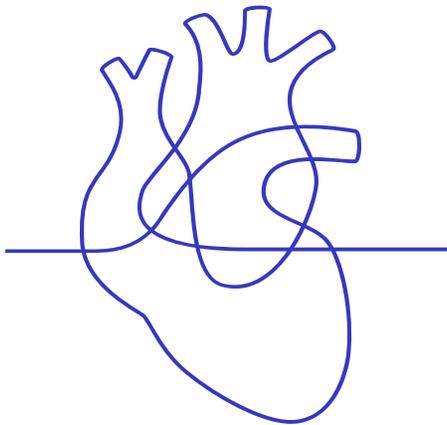
- Assessment of sleep and activity during AECG is feasible; fixed position of patch on the chest may have advantages vs. wrist-worn devices
- Validation of the Zio Sleep and Activity algorithm in a diverse population demonstrated performance comparable to FDA-cleared actigraphy and consumer devices
- Knowledge of sleep and activity periods may provide insights into patient wellness patterns, highlighting its potential for personalized healthcare monitoring

Ongoing research is focused on evaluating AECG arrhythmia findings across different physiological states. Please attend:

Abstract: Characterization of Arrhythmia Occurrence During Sleep and Activity in Patients Undergoing Long-Term Continuous Ambulatory ECG Monitoring

Poster Session: Insight Into Electrophysiologic Realities Gained From the ECG

Monday, Nov 18 1:30 – 2:30 pm (Zone 2); Presentation ID: Mo2148



Thank you !