



DEDiCATES study: Device- detected Sleep Apnea



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Korean Heart Rhythm Society COI Disclosure

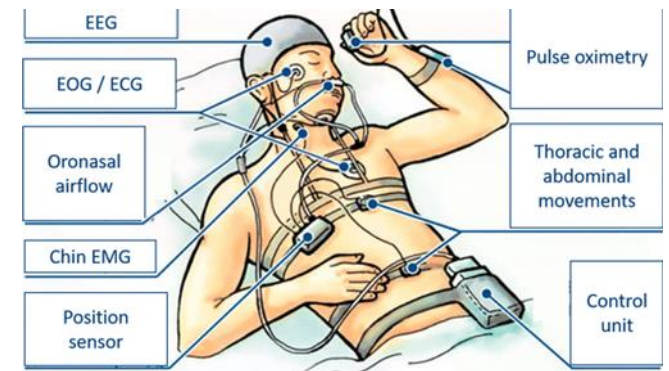
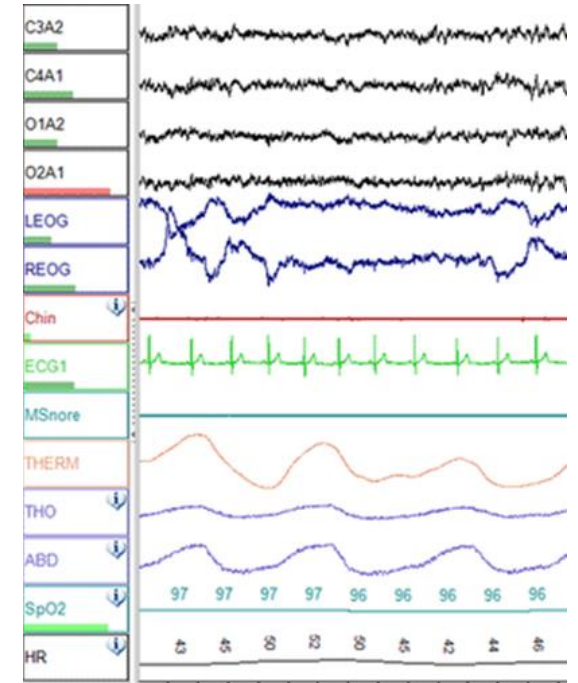
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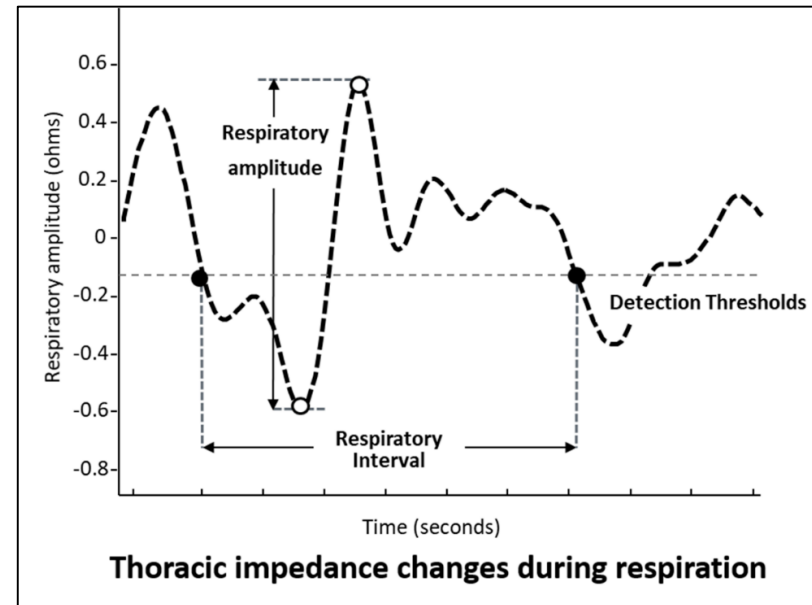
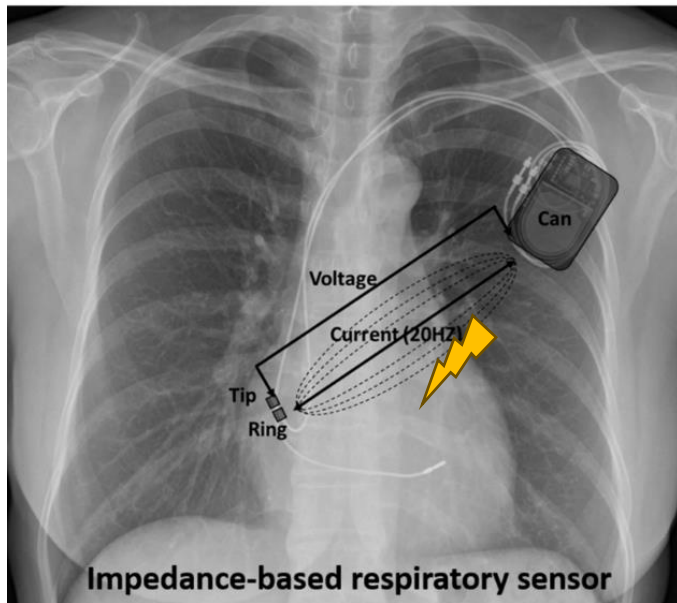
Background

- Sleep-disordered breathing (SDB); sleep apnea
 - Most-common comorbidities in cardiovascular disease patients
 - well-known risk factor for wide range of cardiovascular disease including cardiac arrhythmias
 - up to 50% in CIED patients
- Diagnosis and monitoring of SDB
 - improve quality of life & provide survival benefits
 - Gold standard: polysomnography



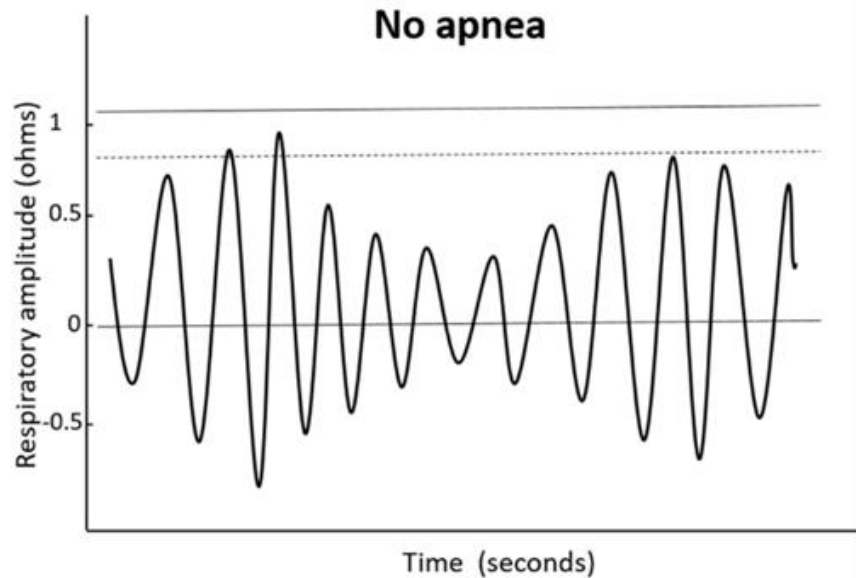
- **Device function for SDB detection (AP scan)**

- Using a respiratory sensor, impedance-based
- Measurement of changes in transthoracic impedance during respiration
- baseline respiratory amplitude and interval (*minute ventilation signal*)

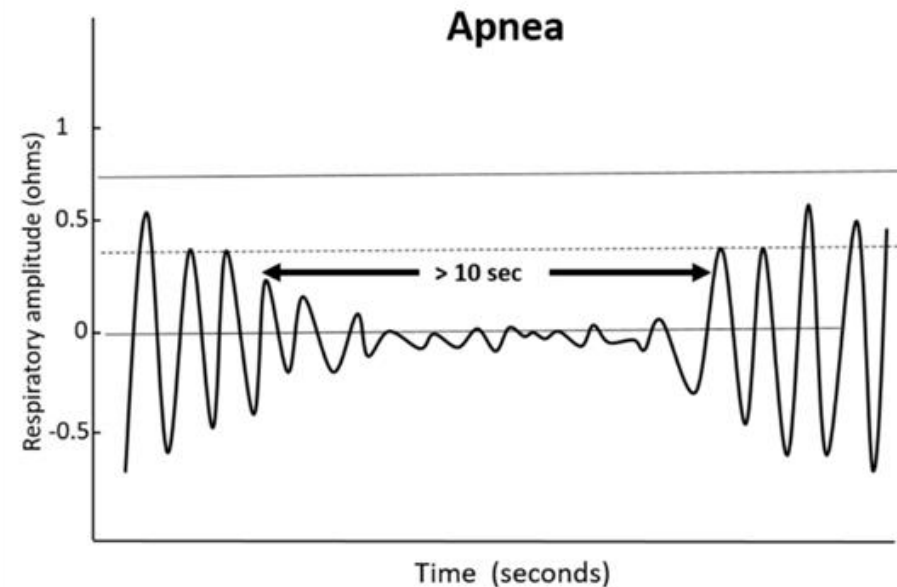


- **AP scan**

- Apnea/hypopnea events = significantly reduced amplitude (below 74% of baseline) for prolonged duration (>10 s)

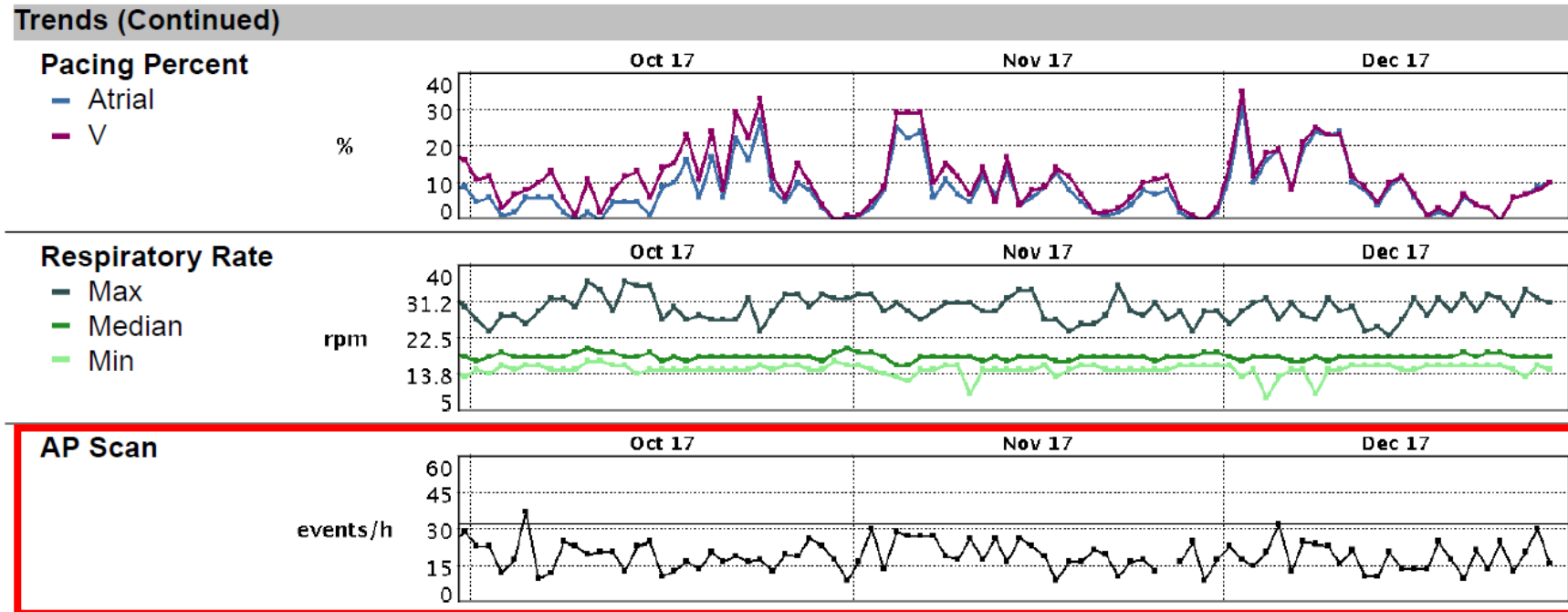


— Baseline smoothed respiratory amplitude
- - - Threshold amplitude (< 74% of baseline)



- **Respiratory Disturbance Index (RDI)**

= average number of apnea/hypopnea events per hour per night



- **Relevant studies**

- Comparable performance in diagnostic accuracy of SDB to conventional PSG
- Night-to-night variability in SDB severity
- Prognostic value of CIED-detected SDB in risk of AF

- Only pacemaker
- Limited to AF occurrence during maximal 1 year follow-up



Introduction

DEvice-**DE**tected **CA**rdiac **T**achyarrhythmic **E**vents and **S**leep-disordered Breathing (**DEDiCATES**) study

- Prospective multicenter observational study; 16 centers in Korea, 2-year follow-up
- Aim: to determine whether device-detected SDB events are associated with increased risk of cardiac arrhythmias or other cardiovascular morbidities



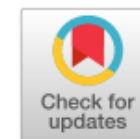
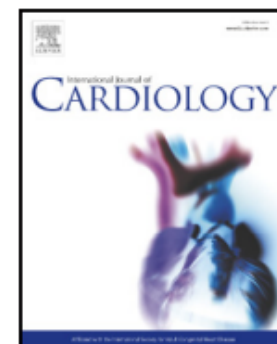


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Rationale, design, and endpoints of the ‘DEvice-Detected CARDiac Tachyarrhythmic Events and Sleep-disordered Breathing (DEDiCATES)’ study: Prospective multicenter observational study of device-detected tachyarrhythmia and sleep-disordered breathing☆

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DEvice-Detected CARDiac Tachyarrhythmic Events and Sleep-disordered Breathing (DEDiCATES) (DEDiCATES)

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Last Update Posted ⓘ 2021-06-30

Study record dates



Study Details

Table View

No Results Posted

Record History

On this page

Study Overview

Contacts and Locations

Participation Criteria

Study Plan

Collaborators and Investigators

Publications

More Information

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Study Overview

Brief Summary:

This prospective multicenter registry study aims to determine whether **device-detected sleep**-disordered breathing events are associated increased risk of cardiac arrhythmias or other cardiovascular outcomes.

Detailed Description:

The prevalence of SDB high in patients with cardiac implantable electronic device (CIED). Recently, device-detected SDB events showed a correlation with sleep-disordered breathing (SDB) diagnosed by polysomnography. Thus, CIED will facilitate early detection and monitoring of SDB in patients with CIEDs. Few studies investigated prognostic value of CIED-detected SDB in risk of cardiovascular events. Therefore, the primary aim is to determine whether device-detected SDB are associated with increased risk of cardiac arrhythmias or other cardiovascular morbidities using a prospective multicenter registry.

OFFICIAL TITLE

Prospective Multicenter Observation Study on the Association Between the Severity of **Device-detected Sleep**-disordered Breathing and the Risk of Cardiac Arrhythmic Events

STUDY START (ACTUAL) ⓘ

2017-04-28

PRIMARY COMPLETION (ESTIMATED) ⓘ

2022-07-31

STUDY COMPLETION (ESTIMATED) ⓘ

2022-07-31

ENROLLMENT (ACTUAL) ⓘ

600

STUDY TYPE ⓘ

Observational [Patient Registr]



- **Patient**

- 600 patients with dual-chamber CIEDs possessing AP Scan™ function

Inclusion

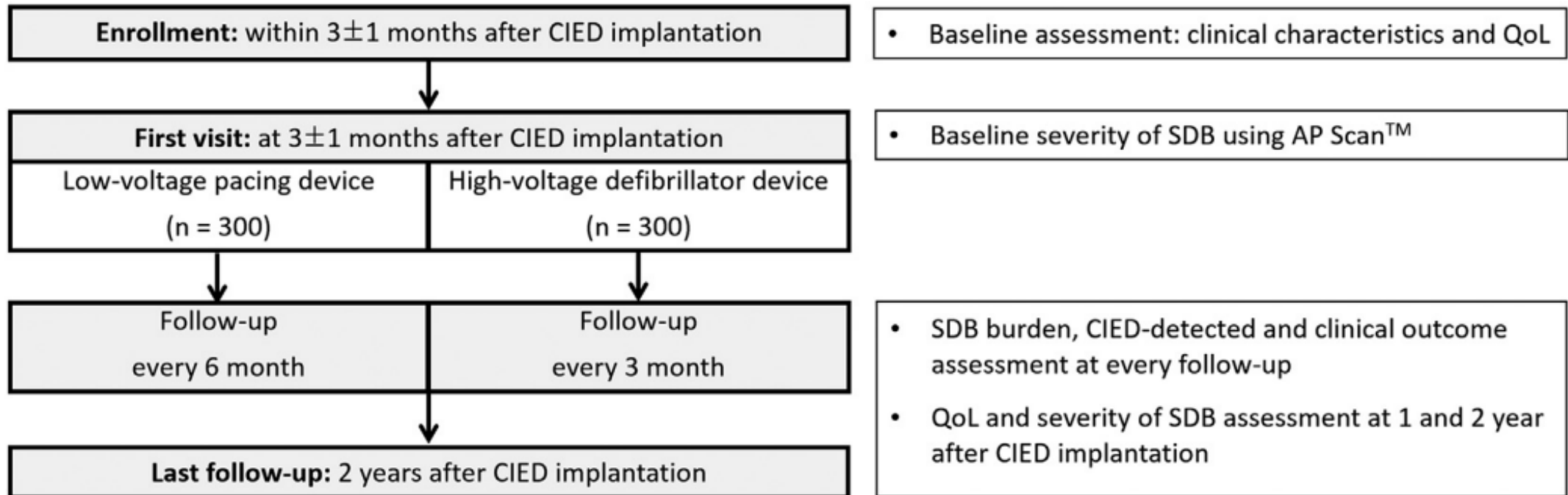
- 1) age \geq 19 years and 2) CHA₂DS₂VASc score \geq 1 in males or \geq 2 in females

Exclusion

- 1) CIED without atrial lead, 2) persistent or permanent AF or AFL, 3) history of catheter or surgical ablation of AF or AFL, 4) \geq moderate degree of valvular steno-insufficiency, 5) chronic obstructive pulmonary disease, 6) under current treatment for SDB, or 7) life expectancy $<$ 1 year



- **Study flow**



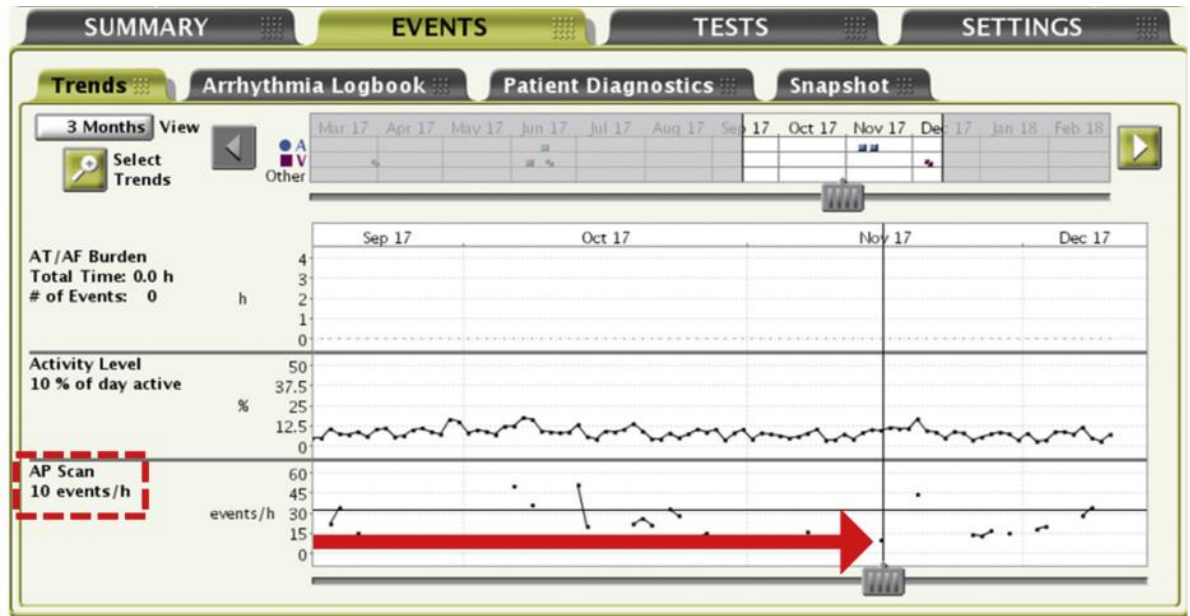
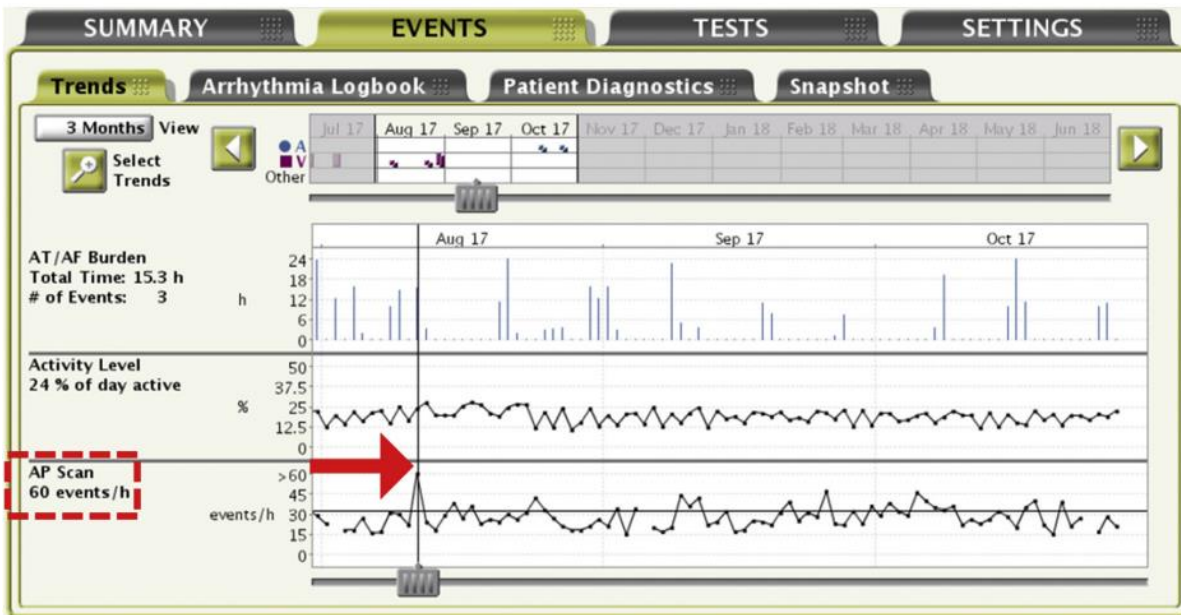
Diagnostic parameters from device interrogation.

	Variables and values
AP scan	Patient sleep time, maximum and minimum RDI value, mean and median RDI, initial severity of sleep apnea, and number of days with $RDI \geq 30$, $15 \leq RDI < 30$, or $RDI < 15$
Atrial high rate episode	Total number of AHRE, total time in AHRE, percentage of time in AHRE, and number of episodes with duration < 1 min, $1 \text{ min} \leq \text{duration} < 1$ h, $1 \text{ h} \leq \text{duration} < 24$ h, $24 \text{ h} \leq \text{duration} < 48$ h, duration ≥ 48 h
Ventricular high rate episode	Number of sustained episodes, date of first sustained episode, number and success of anti-tachycardia pacing or shock therapy
Lead integrity	Sensing amplitudes (mV), sensitivity (fixed or auto gain control, mV), impedance (ohm), pacing threshold (V at ms)

AHRE, atrial high rate episode; RDI, respiratory disturbance index.



- RDI measurement

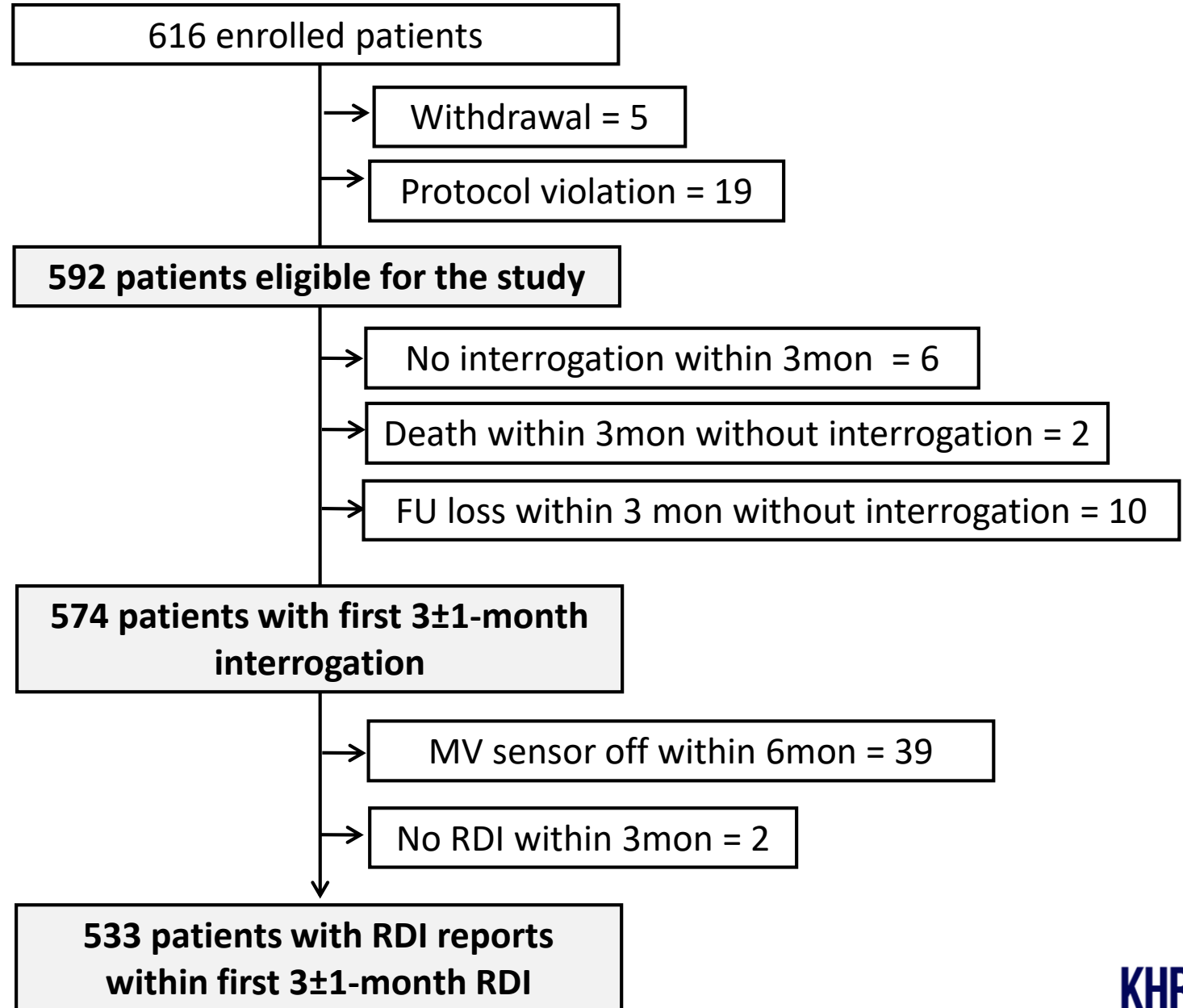


Details of follow-up outcomes.

	CIED-detected and clinical outcomes
<i>Primary outcomes</i>	
Atrial arrhythmia	CIED-detected atrial high rate episode Clinical atrial fibrillation or flutter
<i>Secondary outcomes</i>	
AF-related outcomes	Thromboembolic events, de novo heart failure or decompensation of chronic heart failure, AF progression to persistent/permanent form, ablation therapy of AF
MACE	Cardiac death, stroke, atrial fibrillation or flutter, ventricular tachyarrhythmia, and hospitalization for heart failure
Mortality	Overall and cardiovascular mortality
Ventricular arrhythmia	Clinical events and CIED-detected ventricular high rate episodes, defibrillation therapy (shock or anti-tachycardia pacing)
<i>At 1- and 2-year after CIED implantation</i>	
Quality of life	Assessment by EuroQol five dimensions questionnaire
Severity of SDB	Assessment by Berlin questionnaire



Interim results



Baseline characteristic of total patient (n = 533)

Demographic data	Total patients n = 533
Age (years)	68.4 ± 12.0
Gender (male)	289 (54.2)
Body mass index (kg/m ²)	24.7 ± 3.2
Hypertension	367 (68.9)
Diabetes	171 (32.1)
Heart failure	157 (29.5)
LVEF < 40%	143 (28.4)
LVEF (%)	52.6 ± 16.5
GFR <60ml/min	226 (42.4)
CHA ₂ DS ₂ VASc score	3.2 ± 1.5
CrCl (ml/min)	67.7 ± 30.1
ICD or CRT-D	215 (40.3)

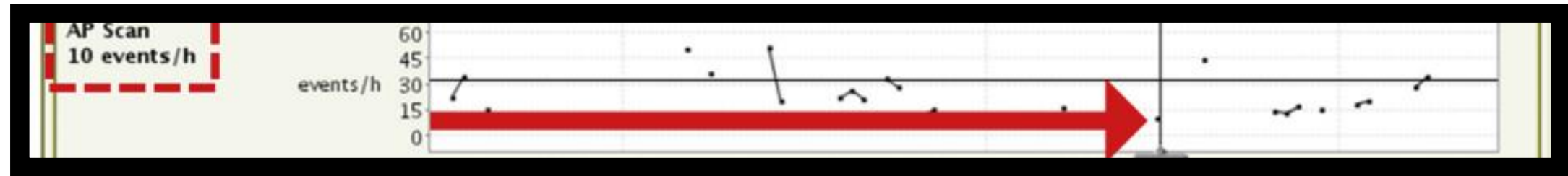
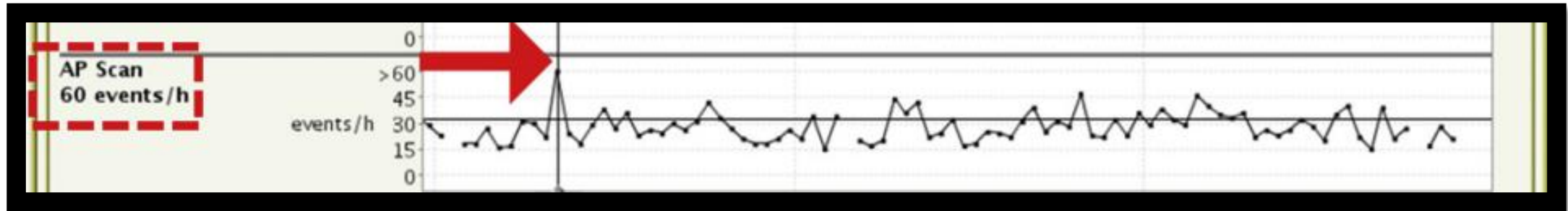


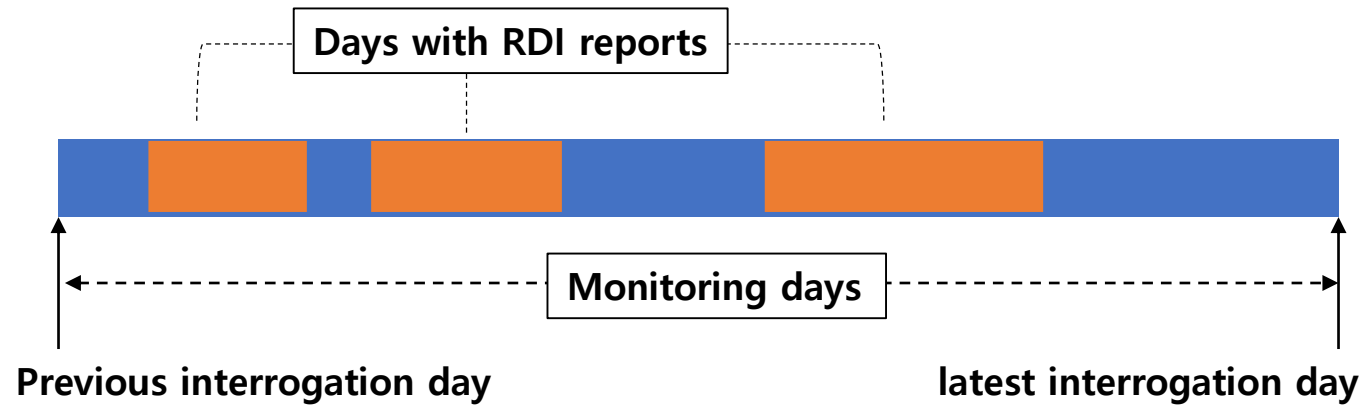
RDI values of total patients (n = 533)

SDB monitoring data	First 3 mons	Total follow-up
Average RDI	33.0 ± 11.1	32.9 ± 10.3
Median RDI	32.4 ± 11.7	32.3 ± 10.9
Maximal RDI	54.9 ± 16.3	64.5 ± 23.6
Minimal RDI	16.6 ± 9.6	12.0 ± 7.0
Max RDI ≥ 30	511 (95.9%)	530 (99.3%)



RDI report day





n = 533	First 3 mons	Total follow-up
Monitoring days	97.9 ± 7.3	654.7 ± 156.0
RDI report days	71.6 ± 31.5	472.0 ± 236.0
RDI report day/ monitoring day (%)	73.1 ± 31.5	72.4 ± 30.7



Summary

- The DEDiCATES study was designed to evaluate the relationships between device-detected SDB and various cardiovascular outcomes in patients with CIEDs during 2-year follow-up.
- This study included largest patient number, and high-voltage defibrillating devices as well as pacemaker.
- SDB is very frequently detected in CIED patients. The optimal RDI-related parameter and its threshold to predict cardiovascular events are planned to be analyzed primarily.
- All device and clinical data collected during 2-year follow-up are being now adjudicated.



Acknowledgement

We thank all the participating centers
for their DEDICATION to the DEDiCATES study



Thank you for the attention

