

PVDOMICS Sleep Core

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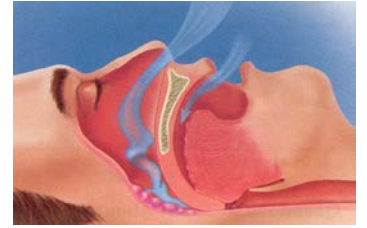


NHLBI Pulmonary Vascular Disease Phenomics Program

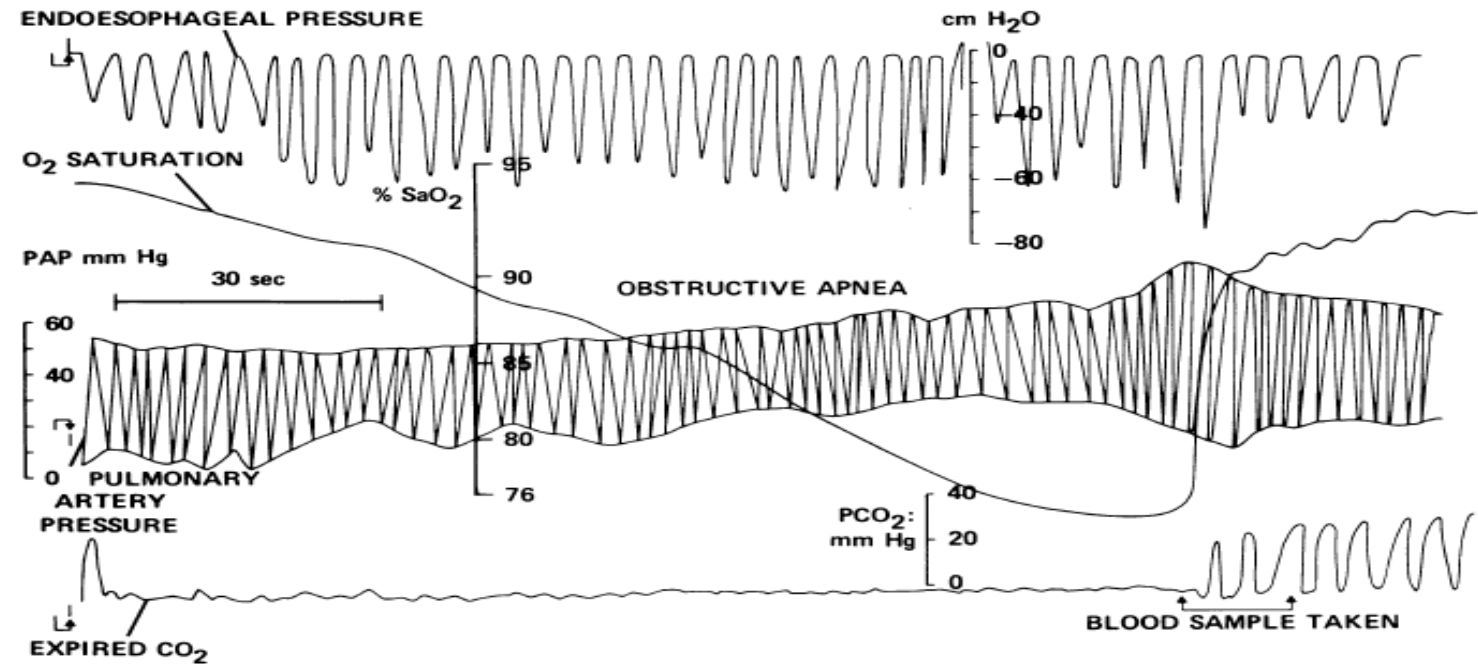
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Obstructive Sleep Apnea

A Highly Prevalent, Under-recognized Physiologic Stressor

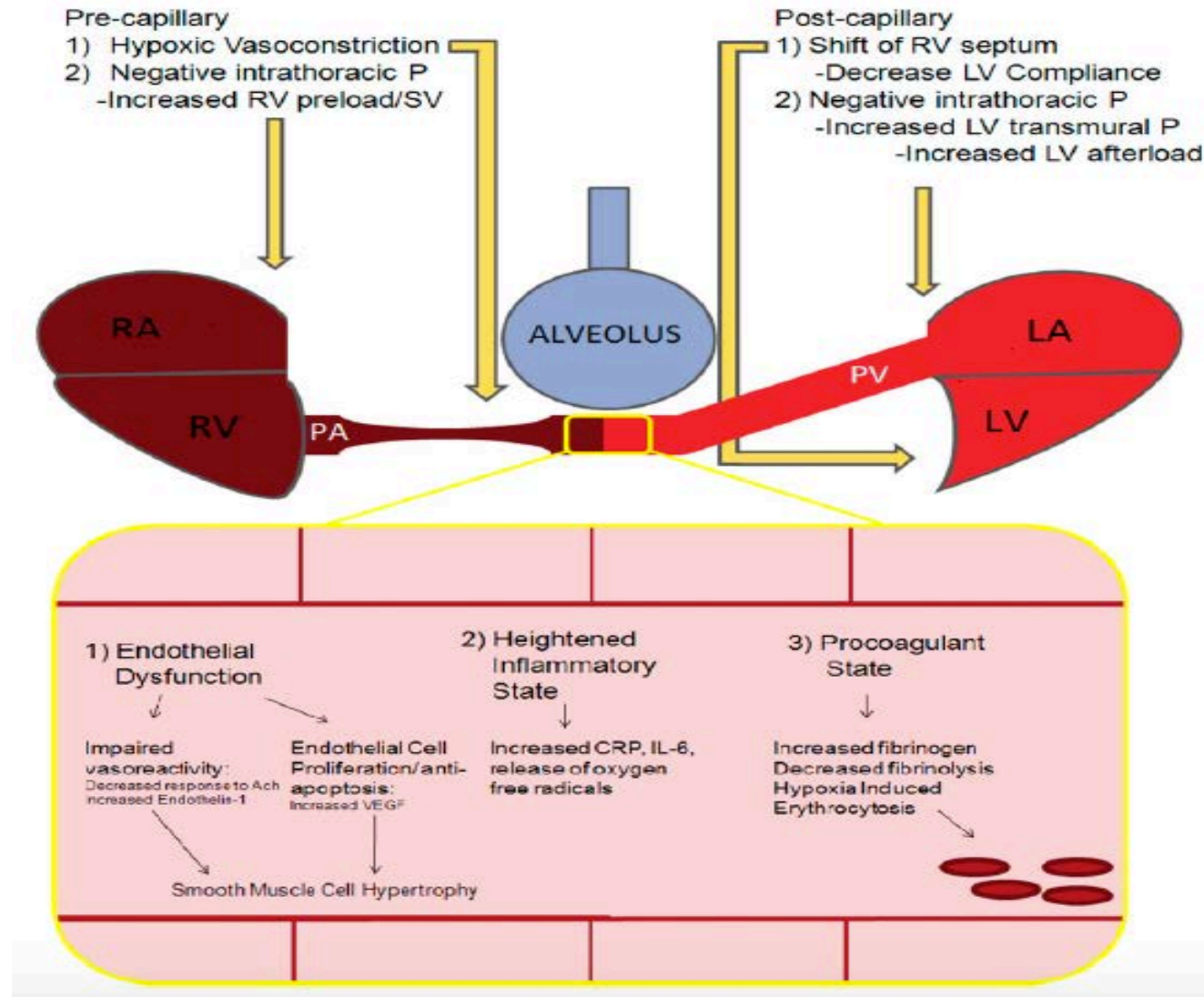


- **17% of the general adult population, increasing with obesity epidemic**
 - Nearly 1 in 15 affected by at least moderate sleep apnea
 - Young et al NEJM 1993, Peppard et al. Am J Epi 2013
 - **85% of cases estimated to be undiagnosed!**
 - Kapur VK et al Sleep and Breath 2002
- **30-40% of patients with CAD**
 - Moore T et al Chest 1996; Schaker et al H Cardiol 1999; Leung RS et al AJRCCM 2001
- **> 50% of patients with diabetes or hypertension or heart failure**



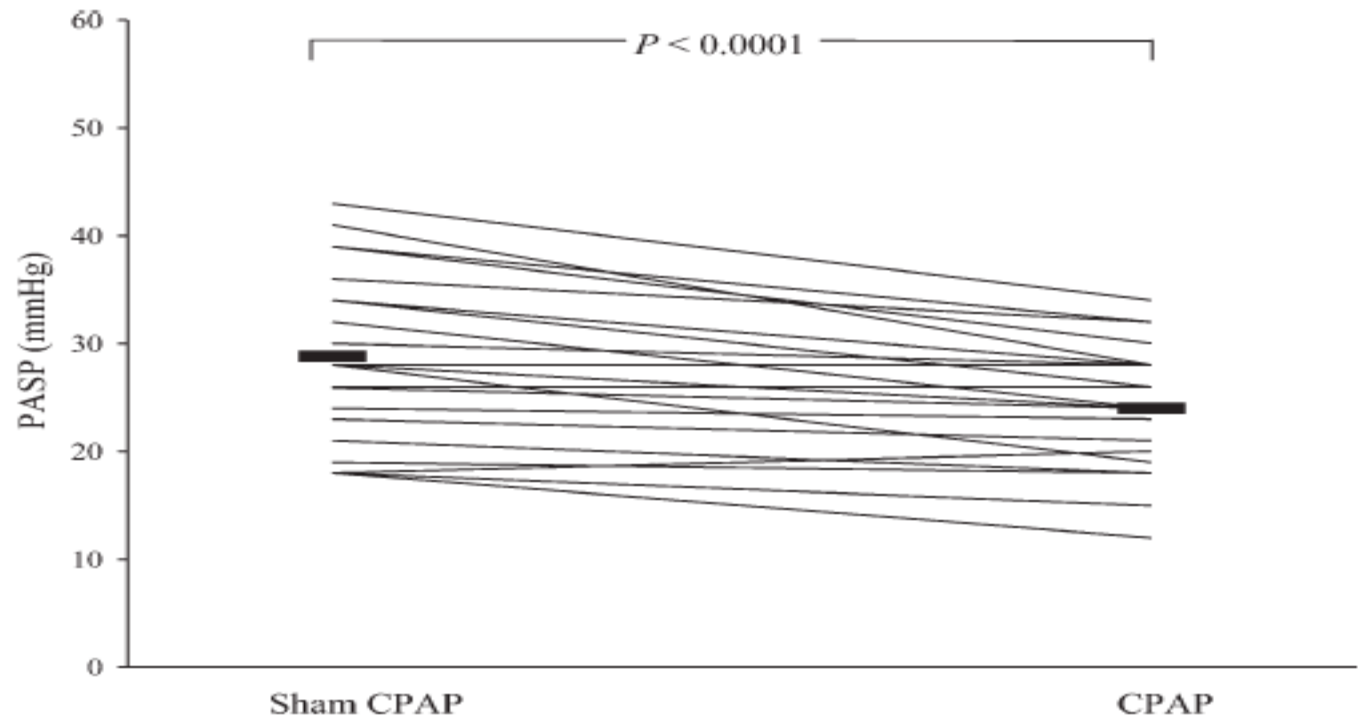
Guilleminault C et al West J Med 1975; 123

Pathophysiological Interactions of Obstructive Sleep Apnea and Pulmonary Hypertension



Effects of CPAP on Pulmonary Arterial Pressures

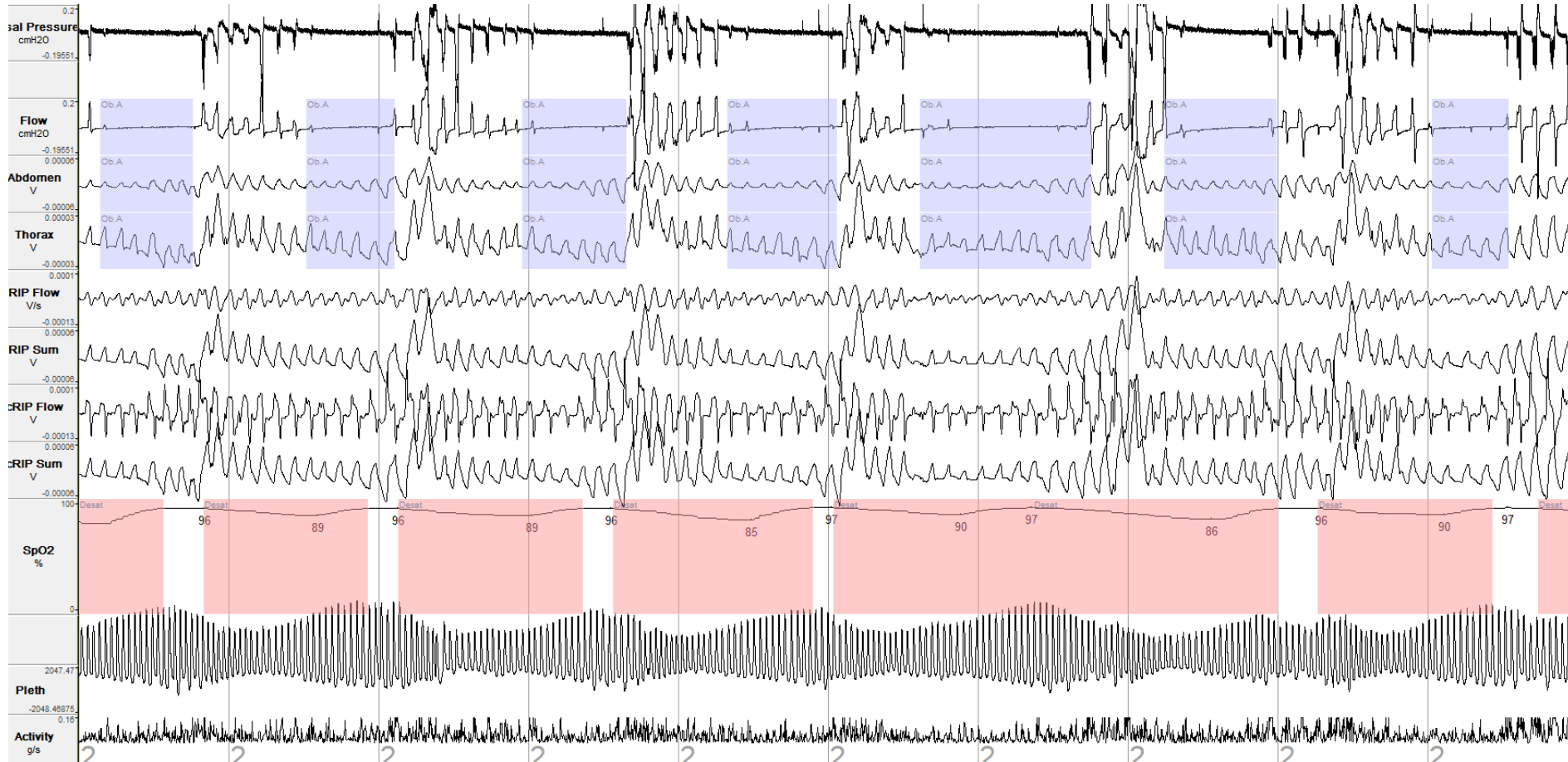
- Randomized, cross-over trial
- Individual values for the PASP after both sham and CPAP in patients with OSA
- Black bar represents mean PASP, changing from baseline 28.9 ± 8.6 mm Hg to 24.0 ± 5.8 mm Hg after 12 wk of CPAP ($P = .0001$)



Higher reduction in PASP after effective CPAP therapy was observed in OSA patients with either LV diastolic dysfunction (7.3 ± 3.3 vs. 1.6 ± 1.8 mmHg, $P = 0.001$) or PH at baseline (8.5 ± 2.8 vs. 2.6 ± 2.8 mmHg, $P = 0.001$)

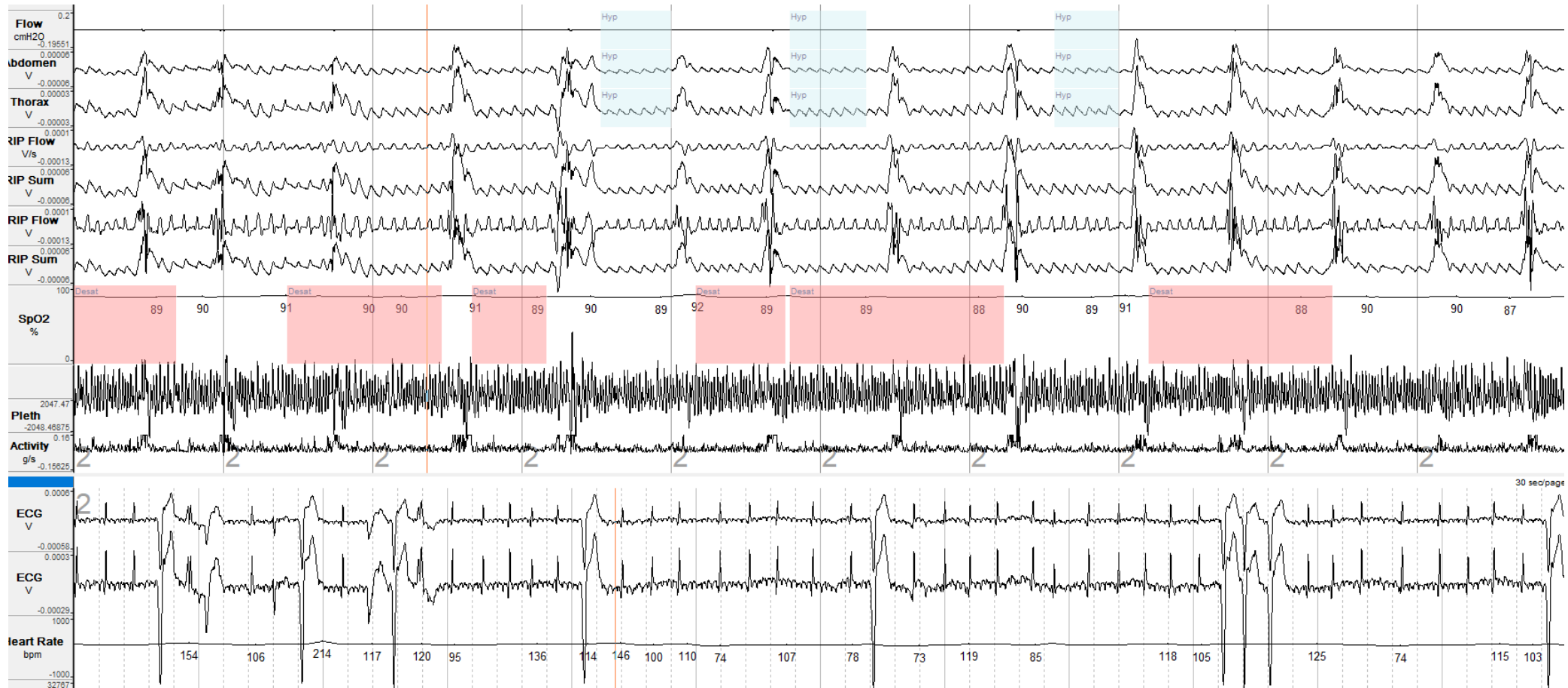
PVDOMICS Sleep Study

Obstructive Apnea



PVDOMICS Sleep Study

ECG Findings



Sleep Study Overview

- As of February 27, 2018, a total of 292 sleep studies have been performed with the first collected sleep study data performed on 01/12/2017.
- The table below provides an overview of the number of sleep studies per center which have passed, failed and for which there was no sleep study performed or it was decided to rely on the contents of a historical sleep study report.

Center	Total Files Received	Passed Studies, 87%	Failed Studies, 12%	Historical Studies	Studies Not Completed *
11	12	8	0	4	Unknown*
21	6	3	0	0	Unknown*
22	62	37	11	14	6
31	46	35	5	2	6
41	128	103	13	8	6
51	27	15	4	5	Unknown*
61	58	54	4	0	2
Total Count	339	255	37	33	20

*Missing final count

Sleep Study Quality

- The majority of the sleep studies have been of excellent/good quality rating (80.4%).
- Failure was due to the oximeter not pairing or turning on.
- The table below provides an overview of the sleep study quality grading system.

Center n=292	Excellent 65.7%	Good 14.7%	Fair 0.1%	Failed 12.6%
11	7	0	1	0
21	3	0	0	0
22	29	4	4	11
31	21	11	3	5
41	80	15	8	13
51	14	1	0	4
61	38	12	4	4
Total Received	192	43	20	37

Medical Alerts

- The Sleep Core identifies incidental findings on participants sleep study recordings and an automatic email is sent to the PI and Study Coordinator.
- The table below provides an overview by centers of the incidental findings discovered.

Center	AHI >50	Oxygen Saturation <85% for >10% sleep time	ECG Findings
11	1	0	0
21	0	0	0
22	0	6	0
31	0	4	0
41	4	4	2-NSVT
51	0	1	1-NSVT
61	0	8	0
Total	5	23	3

Overnight Sleep Monitoring



- ❖ An overnight sleep monitor study will be performed on all **PVDOMICS** study participants unless the participant has had a sleep study within the last year of study enrollment.
- ❖ Work on center logistics to properly capture all consented participants before they leave the center.

PVDOMICS Sleep Core

Certification requirements

- One acceptable overnight pilot study is required to be collected on **both** sleep monitoring units
- Certification studies collected will be on non-participant volunteers
- Must have adequate quality signals recorded for a minimum of 4 hours
- Submission of two acceptable overnight pilot studies that have been converted into EDF format are required

Equipment and Supplies

Equipment and Supplies will be purchased using local clinical center funds

- Nox-T3 Sleep Monitor
- Nox Cannulas
- ECG snap leads and Electrodes
- Nox RIP disposable belts
- Nonin and Wrist Ox
- CPAP adapter and tubing
- Batteries
- Paper tape
- Ziplock sandwich bags



Preparing Nox –T3 Device

- Instructions for the configuration, scheduling device, recording duration, and patient information are described in detail in the Sleep Core MOP Chapter 42
- T3 sleep monitor and Wrist ox need to be turned on for pairing verification
- Contact local rep for more hands on training

*An updated adobe flash installation may be required

Data Transmission

- Sleep study data will be converted to EDF format
- Verify that all electronic data transmitted to the SSH home directory has only PVDOMICS study identifiers
- Filename Format Sleep_XXXXXX_mmddyyyy.edf



File content PVDOMICS ID Date of test

- Log in to SSH with previously assigned account name and password
- Drag and drop file into SSH home directory for PVDOMICS on DCC server
- Document transfer date in Q13 on Form 152
- DCC will move file out of home directory for processing
- Files will be opened, reviewed .and scored at the Sleep core.
- Sleep reports will be emailed back to the centers once scoring has been completed.

Sleep Study Forms

Below are forms that are completed at the Clinical Center:

- Form 150: Clinical Center Participant Initial Sleep
- Form 151: Participant Sleep Study Questionnaire
- Form 152: Clinical Center Sleep Download and Transmittal
- Form 155: Clinical Core Historical Sleep Study Report Transmission
- Form 156: Core Alternative/Historical Sleep Study Report Review

Overcoming Challenges

- Sleep monitoring return
 - ❖ Schedule device to be returned on a follow up visit
 - ❖ Schedule to have a courier pick up from home
 - ❖ Send home a mailing packet
- Purchase a third unit using local center funds to improve efficiency
- Conquering failed studies
 - ❖ Turn device on and double check that it has been accurately paired
 - ❖ Contact a local Vyair representative for additional training

Sleep Core Contact Information

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