

A young child is smiling and holding a glowing light stick at a night festival. The background is filled with colorful bokeh lights in shades of blue, green, and yellow. The child is wearing a light-colored t-shirt with a graphic design.

# Advances in OSA Management: Treatment of Positional OSA

# Disclosure

- Philips Employee

# Objectives

- Define positional obstructive sleep apnea (POSA)
- Describe the clinical evidence for recognizing POSA
- Discuss the different therapies for treating POSA



# Question 1

Question:

Does your lab currently identify body position during the sleep study?

Answer:

Yes

No

# Question 2

Question:

If yes, how do you currently treat these patients?

Answer:

No treatment

CPAP

Mechanical positional treatment devices, such as tennis balls.

Electronic positional treatment devices, such as NightShift or NightBalance

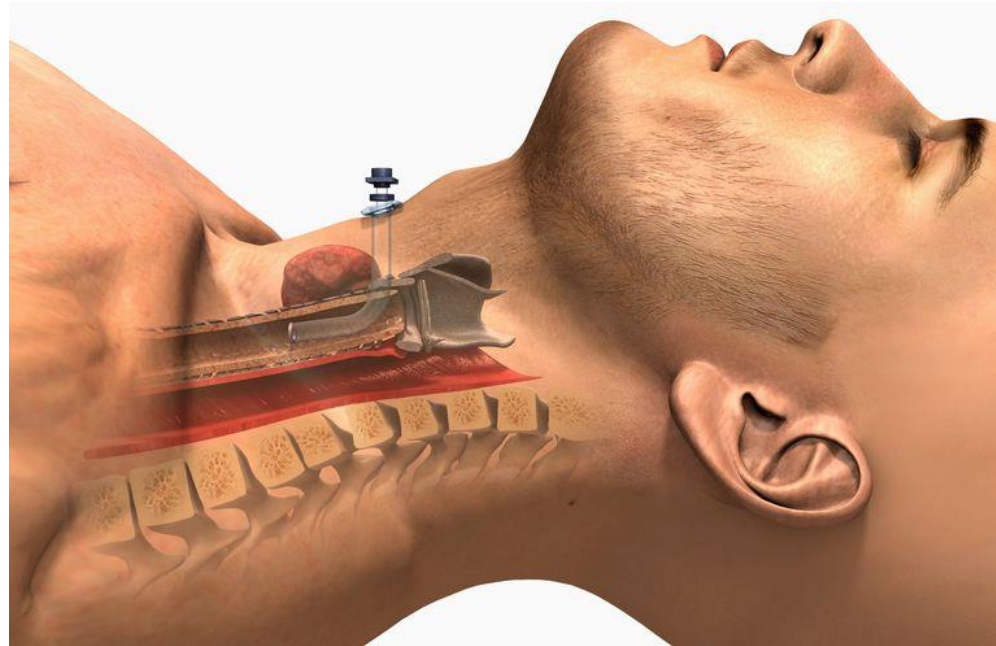
# In 1965

Obstructive sleep apnea (OSA)  
was 1<sup>st</sup> described<sup>1</sup>



# In 1969

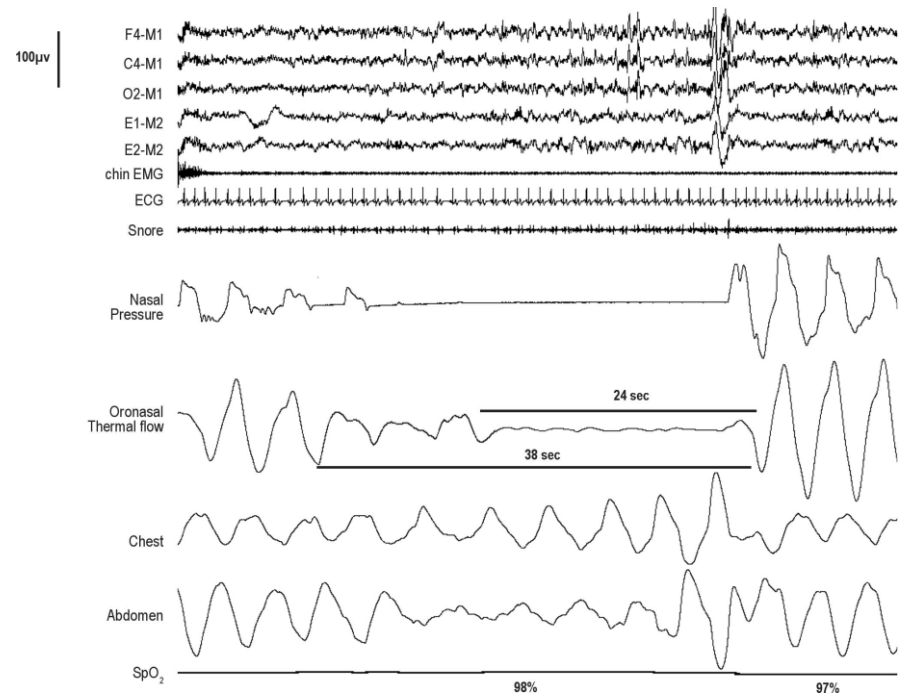
## Tracheostomy to bypass the upper airway affected by OSA<sup>1</sup>



Retrieved from <https://www.verywellhealth.com/the-use-of-tracheostomy-in-sleep-apnea-3015242> 6.5.2019

# In 1976

## Scoring parameters for OSA are established



Berry, R. B. (2012). Rules for Scoring Respiratory Events in Sleep: Update of the 2007 AASM Manual for the Scoring of Sleep and Associated Events. Retrieved from <http://jcsn.aasm.org/ViewAbstract.aspx?pid=28684>

# In 1981

## Sullivan uses PAP therapy



Vortex Blower with Sullivan/Bruderer Soft Mask

# In 1990

## Sanders uses Bi-level PAP therapy



# In 1983 and 1984

- 1983: De Konick recognized that there could be a positional component to OSA<sup>1</sup>
- 1984: Cartwright suggested interventions could keep patients off of their backs<sup>2</sup>



1. De Konick, J. (1983) Sleep Positions in the Young Adult and Their Relationship with the Subjective Quality of Sleep et al Sleep, 6(1):52-59  
2. Cartwright, R. (1984) Effect of Sleep Position on Sleep Apnea Severity Sleep, 7(2): 110--114

# Positional Obstructive Sleep Apnea

## What is POSA?

Positional obstructive sleep apnea (POSA) is a specific diagnosis, distinct from other types of OSA. It is a condition in which the vast majority of apneic events occur during supine sleep.

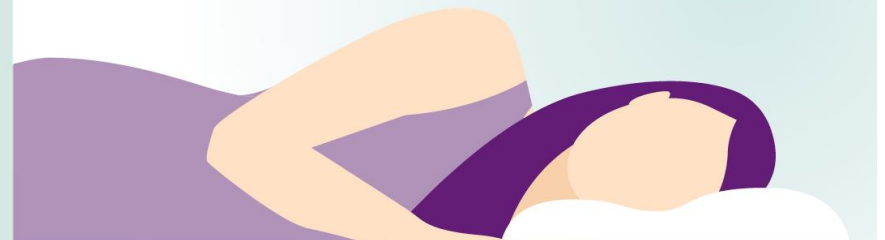
Cartwright\* criteria uses the following to define and diagnose POSA:

$$AHI_{\text{supine}} \geq 2 \times AHI_{\text{non-supine}}$$

With POSA, the vast majority of apneic events occur during **supine sleep**



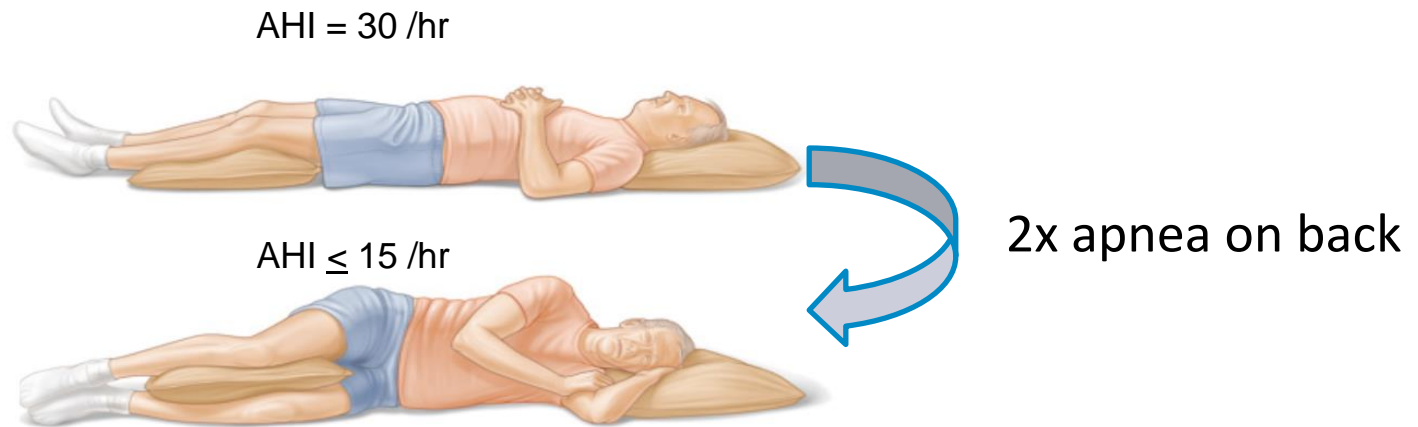
Focus of treatment is to help patients **sleep on their side**



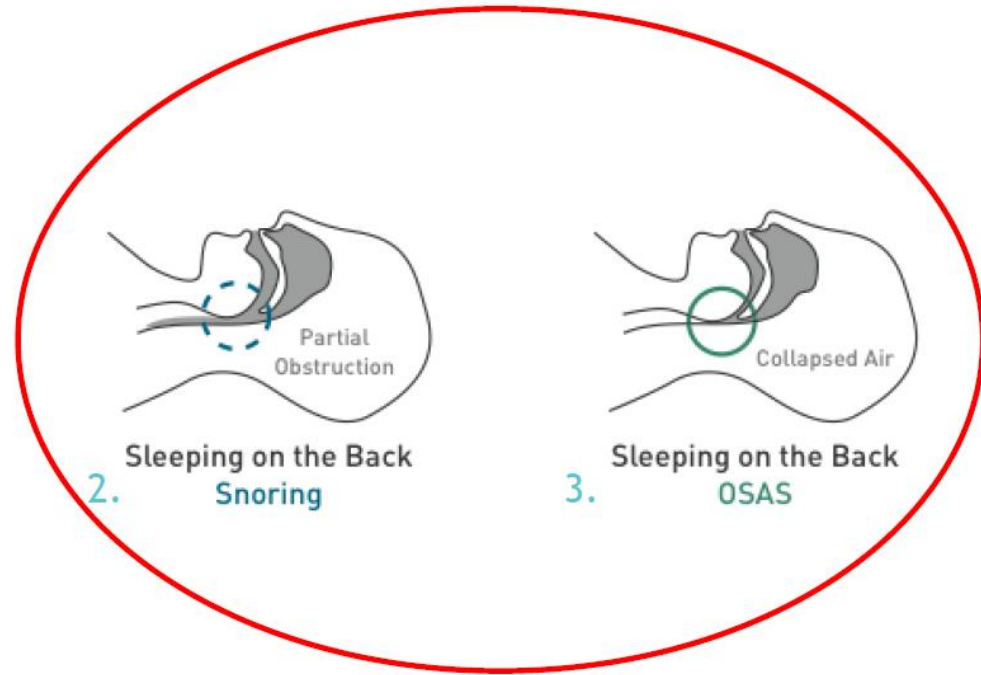
\*Cartwright, RD. Effect of Sleep Position on Sleep Apnea Severity. *Sleep*. 1984;7(2):110-14.

# Positional Sleep Apnea (POSA)

POSA definition = AHI reduction of  $\geq 50\%$  from supine to non-supine position



# Positional Sleep Apnea (POSA)



# Exclusive Positional Sleep Apnea (ePOSA)

AHI = 20 /hr



AHI < 10/hr

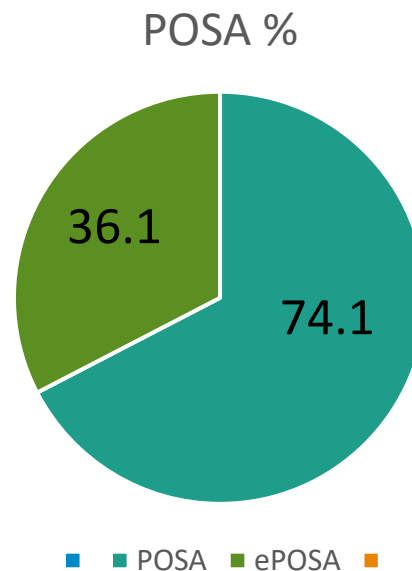


Supine AHI >2x Non-supine AND

Non-supine <10/hr

# Positional OSA Prevalence

- POSA prevalence in 74.1% of OSA patients
  - ePOSA was present in 36.1% of OSA subjects<sup>1</sup>
- Main characteristics of Positional OSA population:
  - Lower AHI
  - Lower BMI with less abdominal obesity (men)

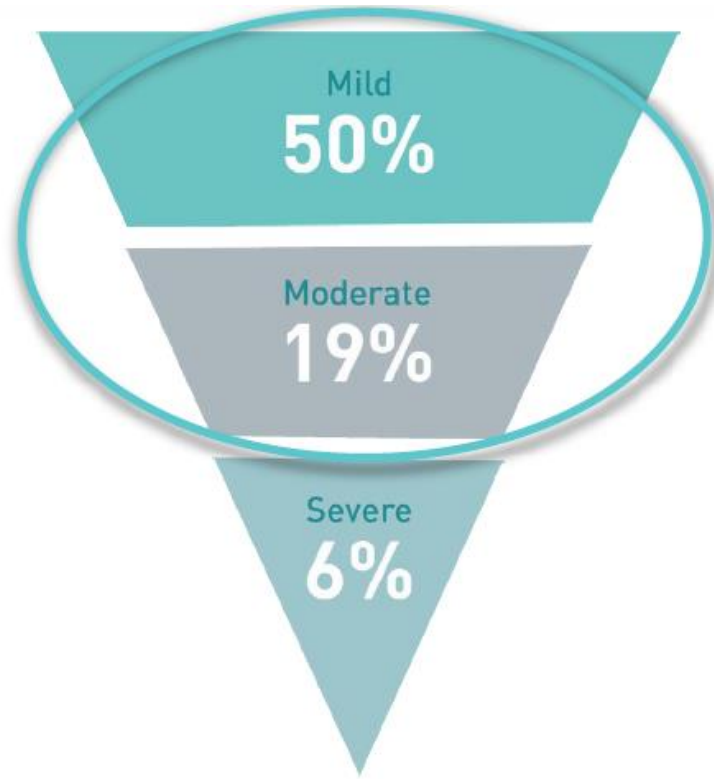


# Prevalence and determinants

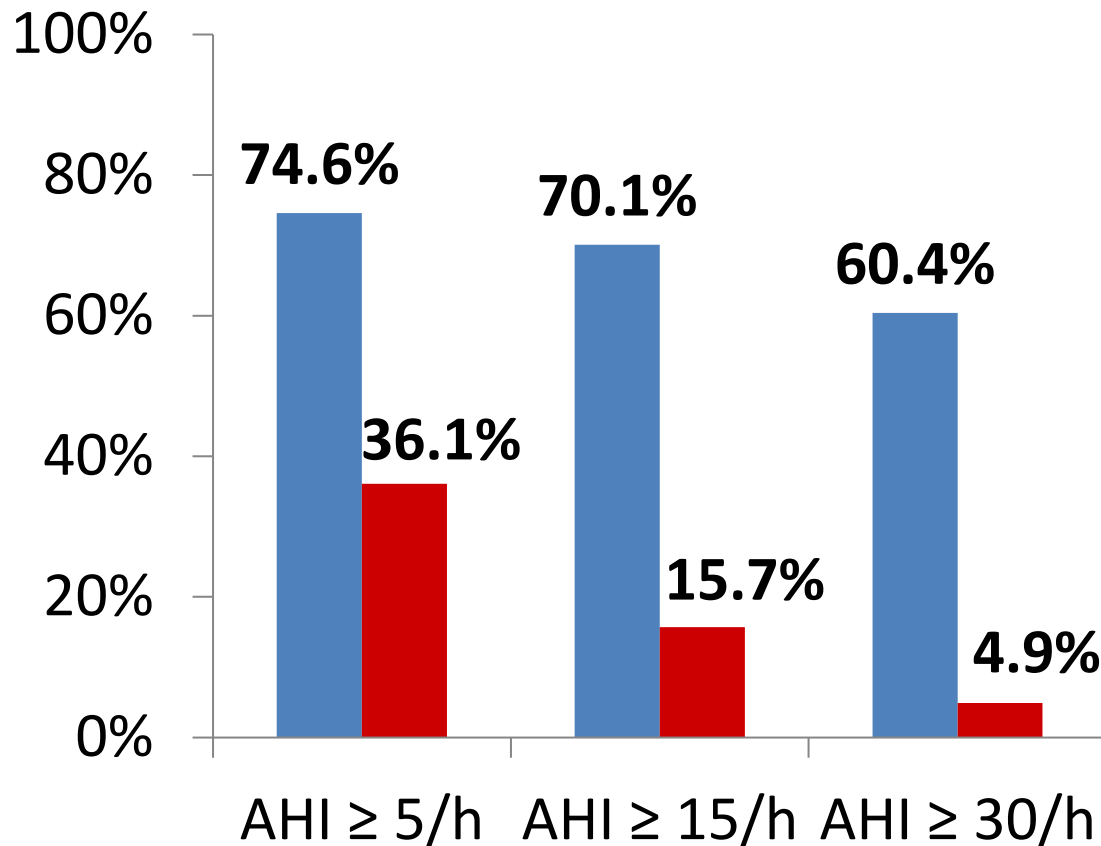
Authors	OSA (n)	Prevalence POSA or POSA excl (%)	Determinants of POSA
Oksenberg (1997)	574	56%	Lower age, lower BMI. Lower AHI, Longer MSLT
Mador (2005)	248	27.4% (excl)	Lower age, BMI, and neck circ.
Ji-Hun (2011)	1170	75%	Lower BMI, neck, AHI and ESS
Tanaka (2009)	462	74%	Lower BMI, AHI, and ESS Male sex
Teerapraipruk (2012)	144	67% 47% (excl)	Lower snoring Lower AHI

# Positional OSA Prevalence

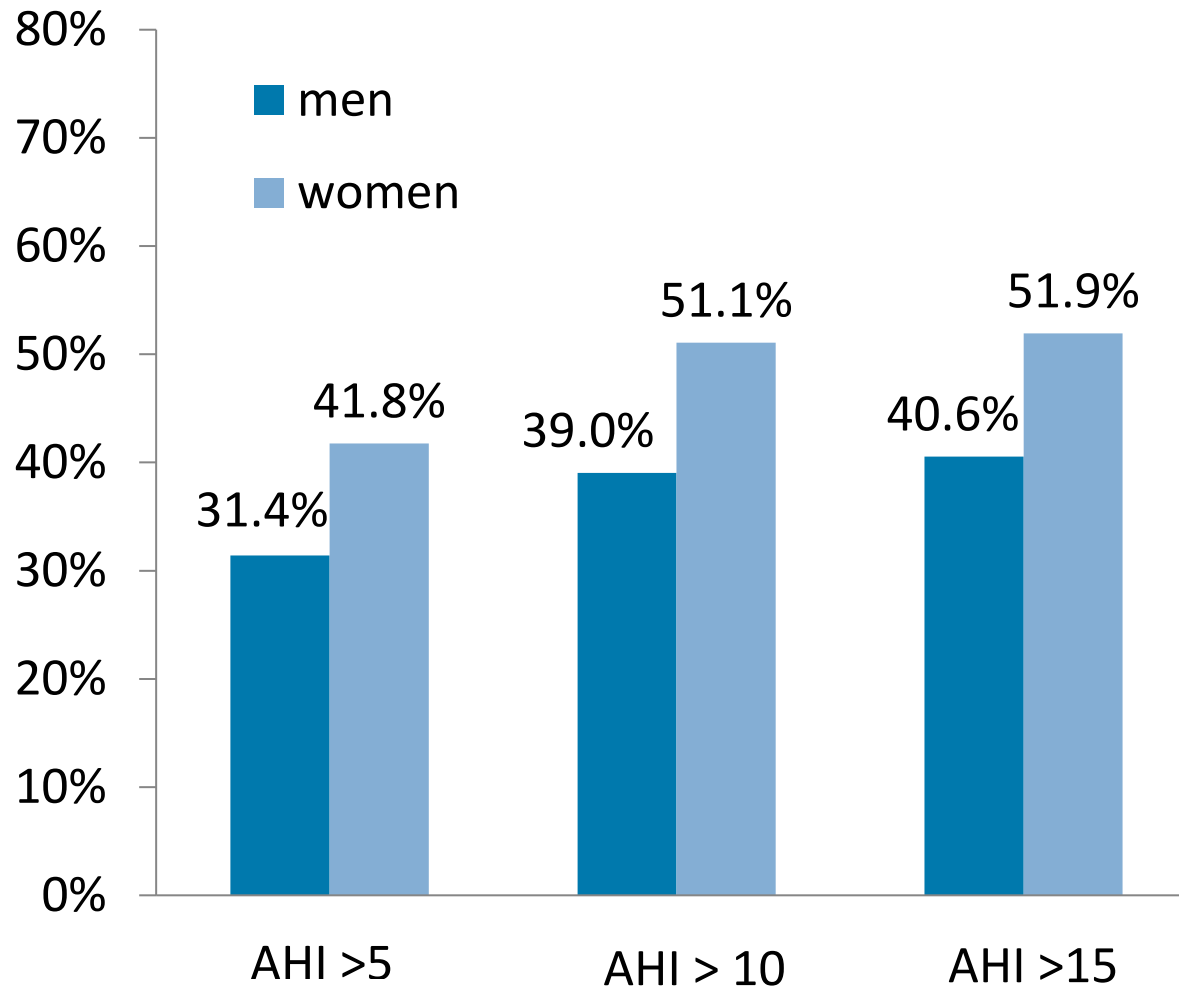
## POSA prevalence among OSA severities<sup>1</sup>



# Prevalence of POSA and ePOSA according to different AHI thresholds



# Prevalence of ePOSA according to sex and AHI thresholds



# Question 3

Question:

What is the definition of ePOSA?

Answer:

$$AHI_{\text{supine}} \leq 2X AHI_{\text{non-supine}}$$

Supine AHI > 2X non-supine and non-supine < 10/hr.

AHI reduction of  $\geq$  50% from supine to non-supine

# Positional Obstructive Sleep Apnea Treatment

# Existing Treatment Alternatives

Current treatments have potential challenges



## CPAP

- Low Adherence
- Obtrusive
- Multiple components
- Cleaning/maintenance
- Side Effects -



## OAT

- Dental contraindications
- Difficult to trial
- Mixed response rate
- Compliance data reporting
- Side Effects -



## Surgery

- Strict selection criteria
- High cost
- Low response rate
- Side effects -

# Positional OSA therapy vs. CPAP

Positional OSA accounts for anywhere between **36-47%<sup>1</sup> of all OSA patients**, most of whom receive CPAP as a 1st line of therapy, but...

- Various studies have shown that non-adherence to CPAP is typically between 20%-40% of patients
- Implies as high as **20% of all OSA patients** may have **POSA AND** are non-compliant to PAP therapy

1. A recent study by Heinzer et al 2018 demonstrates that exclusive POSA was present in between 36% and 47% of OSA subjects.\* 36% of patients met the criteria of POSA and had a non-supine AHI of less than 5. 47% of patients met the criteria of POSA and had a non-supine AHI of less than 10

# Indications for use

## Indications for use

- Prescription use
- Adult population
- AHI supine  $\geq$  2x AHI non-supine
- AHI non-supine  $<$  20

## Contra-indications

- Using another medical aid that can be affected by mild vibrational stimuli on the chest
- Required to sleep in supine due to medical condition (e.g. shoulder injury, back surgery or osteoarthritis)
- Only able to sleep in an upright position or requires more than 2 pillows during sleep

## Treatment is suitable for:

- Newly diagnosed patients with POSA
- Non-compliant patients to CPAP or MAD that have POSA
- Post-surgery patients (e.g. Upper airway surgery or hypoglossal nerve stimulation) with residual POSA
- Combination treatment (e.g. with CPAP or MAD), with expected treatment outcome expectation

# Challenges and Opportunities in Treating Positional OSA

- Addressing challenges with many available therapies
  - Non-adherence is a barrier to both traditional OSA therapy and passive positional devices (tennis balls and other bulky devices worn on the back during sleep).



Non-adherence with PAP therapies ranges from **29%-83%**<sup>1,2</sup>

1. Sawyer, AM. et al, A systemic review of CPAP adherence across age groups: clinical and empiric insights for developing CPAP adherence interventions, Sleep Med Review, 2011 Dec, 15(6): 343-56.

2. Weaver, T. et al, Adherence to Continuous Positive Airway Pressure Therapy: the Challenge to Effective Treatment, Proceedings of the American Thoracic Society, Vol5, 2008)

# Positional OSA Devices Review

## Therapy options to treat positional OSA:

- CPAP
  - Patients may prefer less-invasive, mask-free options
  - Adherence issues
- Mechanical devices
  - Examples: Tennis ball technique and other bulky objects worn on the back
  - Adherence issues & historical lack of data feedback provided to clinicians
- Electronic devices
  - Example - Philips NightBalance
  - Provides data feedback
- Mandibular advancement devices
- Surgery

# Treatment Types



# Treatment Types

## Mechanical Devices



## Electronic Devices



# Limitations of Positioning Devices

- Discomfort
- Disruption of sleep architecture
- Acclimation to constant stimulation
- No objective adherence or efficacy data
- No clear guidelines on duration of treatment to entrain
- No clear guidelines as to interval to restudy to confirm continued efficacy

# Mechanical Devices Issues

Study	Device	AHI reduction at baseline	Time	Still using device
Oksenberg et al. 2006	Tennis Ball		6 months	38%
Wijkstra et al. 2015	Waistband	14.5 (10.7-19.6) to 5.9 (3.1-8.5)	13 months	35%
Wenzel et al. 2007	Vest		24 months	27%
Bignold et al. 2009	Tennis Ball		30 months	19%

While mechanical devices reduce the AHI, long-term adherence is poor. Most drop-outs cite comfort as a problem.

# Conclusion: Key Take-Away Message

## Mechanical Devices

- There are two types of devices that can be used to treat patients with positional obstructive sleep apnea that are best defined by their mode of action
  - Mechanical devices: bulky mass worn on the back
  - Electronic devices: provide electronic stimuli to prompt patient to roll onto their back
- Mechanical devices reduce the AHI
- Long-term adherence is poor
- Comfort is a particular issue

# Clinical Evidence

# POSA Practice Parameters

## AASM OSA Guidelines

- Considered a 2<sup>nd</sup> line therapy or supplement to primary therapy if low AHI in the non-supine position

United States



# Clinical Validation

Clinical trial data published in 10 peer-reviewed medical journals



Recent DeRuiter 12M Durability Publication

Van Maanen et al. The sleep position trainer: a new treatment for positional obstructive sleep apnoea, *Sleep Breath* 2103; 17:771-779

Van Maanen & de Vries, Long-Term Effectiveness and Compliance of Positional Therapy with the Sleep Position Trainer, *SLEEP* 2014; Vol. 37, No. 7

Eijsvogel et al, Sleep Position Trainer versus Tennis Ball Technique, *Journal of Clinical Sleep Medicine* 2015; Vol. 11, No. 2

Dieljtsens et al, A promising concept of combination therapy for positional obstructive sleep apnea, *Sleep Breath* 2015; 19:637-644

Benoist et al, Positional therapy in patients with residual positional obstructive sleep apnea after upper airway surgery, *Sleep Breath* 2016;

Benoist et al, A randomized, controlled trial of positional therapy versus oral appliance therapy, *Sleep Medicine* 2017; 34:109e117

De Ruiter et al, Durability of treatment effects of the SPT versus oral appliance therapy in positional OSA: 12-month follow-up, *Sleep Breath* 2017;

Laub et al, A Sleep Position Trainer for positional sleep apnea: a randomized, controlled trial, *Journal of Sleep Research* 2017;

# Three Month Data. Benoist et al. 2017

Sleep Medicine 34 (2017) 109–117



Contents lists available at [ScienceDirect](#)

## Sleep Medicine

journal homepage: [www.elsevier.com/locate/sleep](http://www.elsevier.com/locate/sleep)



### Original Article

## A randomized, controlled trial of positional therapy versus oral appliance therapy for position-dependent sleep apnea



Linda Benoist <sup>a, b, \*</sup>, Maurits de Ruiter <sup>c, d</sup>, Jan de Lange <sup>c, d</sup>, Nico de Vries <sup>a, d, e</sup>

<sup>a</sup> Department of Otorhinolaryngology Head and Neck Surgery, OLVG West, Amsterdam, The Netherlands

<sup>b</sup> Department of Otorhinolaryngology and Head and Neck Surgery, Erasmus University Medical Center, Rotterdam, The Netherlands

<sup>c</sup> Department of Oral and Maxillofacial Surgery, Academic Medical Center, Amsterdam, The Netherlands

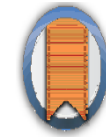
<sup>d</sup> Department of Oral Kinesiology, Amsterdam, The Netherlands

<sup>e</sup> Department of Otolaryngology and Head and Neck Surgery, Antwerp University Hospital, Antwerp, Belgium

## Conclusions

Benoist et al. 2017

- After three months, OAT and SPT are **equally effective** in reducing the AHI and other efficacy measures in mild-to-moderate POSA patients (13.9 to 8.7 on SPT; 13.2 to 8.1 OAT)
- Adherence was **high and similar** on both OAT and SPT (89.3% SPT; 81.3% OAT)
- There were **no safety concerns**



# Durability of treatment effects of the Sleep Position Trainer versus oral appliance therapy in positional OSA: 12-month follow-up of a randomized controlled trial

Maurits H. T. de Ruiter<sup>1</sup> & Linda B. L. Benoist<sup>2,3</sup>  & Nico de Vries<sup>2,4,5</sup> & Jan de Lange<sup>1,4</sup>



## Conclusions

De Ruiter et al.

- The **efficacy of SPT was maintained** over 12 months of therapy in patients with mild to moderate POSA
- The efficacy of SPT was **comparable to that of OAT**
- **Adherence to both treatment modalities was high**, and similar in the two groups
- There were **no safety concerns**

# NightBalance Sleep Position Treatment Device vs Auto-Adjusting Positive Airway Pressure for Treatment of Positional Obstructive Sleep Apnea

## The POSAtive Study

Dr. Richard Berry, National PI, UF Health, FL  
Matthew Uhles, MS, Clayton Sleep Institute (our Central Scoring), MO  
Dr. Brian Abaluck, Paoli Hospital, PA  
Dr. David Winslow, Kentucky Research Group, KY  
Paula Schweitzer, PhD, St. Lukes, MO  
Dr. Raymond Gaskins, Med One Sleep, NC  
Dr. Robert Doekel, Sleep Disorders Center of Alabama, AL  
Dr. Helene Emsellem, Center for Sleep and Wake Disorders, MD



Example of SPT

Berry, Richard B. et al, NightBalance Sleep Position Treatment Device versus Auto-adjusting Positive Airway Pressure for Treatment of Positional Obstructive Sleep Apnea, Journal of Clinical Sleep Medicine, 2019 ,Vol. 5, No.7, 947-956

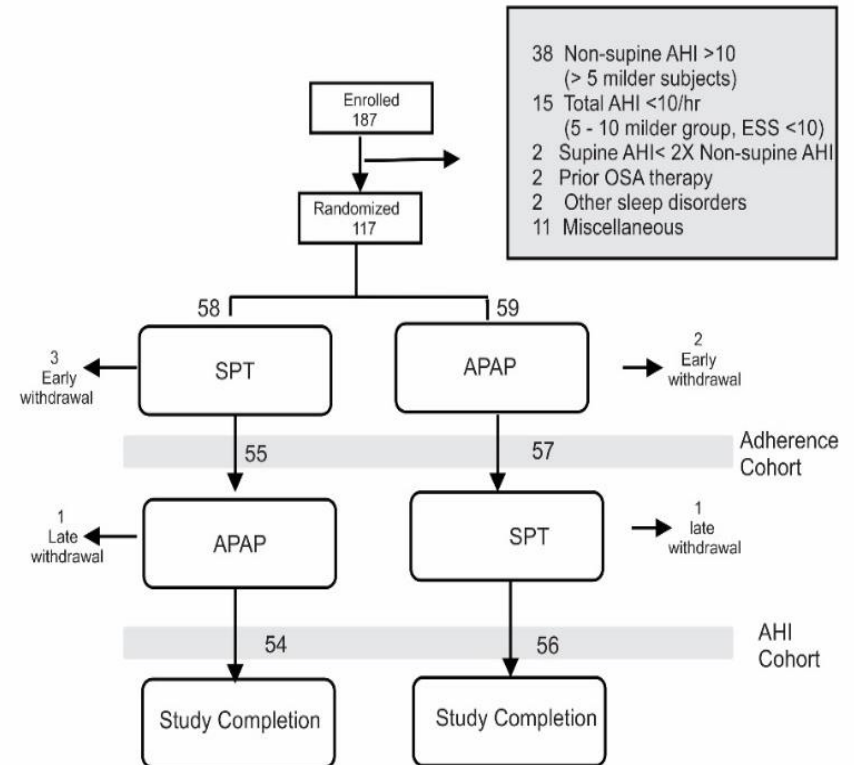
# The POSActive Study

## Study Design

- Prospective, multi-center, randomized crossover study
- Eight (8) US sites with 110 subjects
  - 6 weeks of home use and treatment PSGs with both SPT and APAP

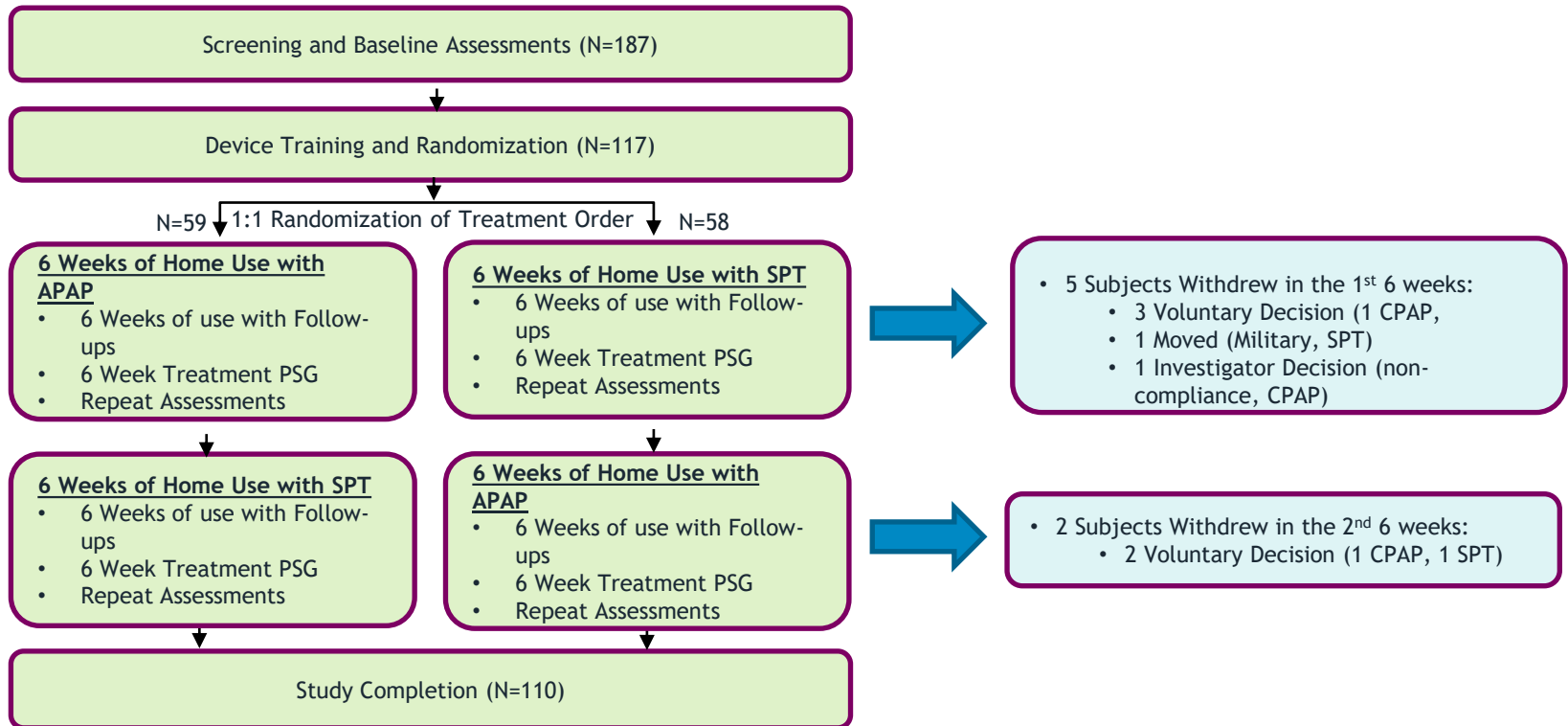
## Primary Endpoints

- Efficacy of non-inferiority within 5 AHI points to APAP
- Adherence greater than 45 minutes to APAP



# The POSActive Study

## Methods



# The POSAtive Study

## Demographics

Characteristic*	N=117
Male Gender, N (%)	70/117 (59.8%)
Age	51.1 ± 12.6 (24–76)
Neck Circumference	15.5 ± 1.45 (12–19)
Heart Rate	72.1 ± 12.03 (41-100)
Systolic Blood Pressure	124 ± 15.2 (92-165)
Body Mass Index**	30.3 ± 5.5 (19.4-53.5)
Baseline AHI	21.2 ± 8.2 (9.5-55.6)
Baseline ESS	10.0 ± 4.9 (0-24)

\*Mean +/- SD (min-max)

\*\*APAP First Group mean of 31.3; SPT First Group mean of 29.2 (0.042 per Students t-test. All others non-significant)

Berry, Richard B. et al, NightBalance Sleep Position Treatment Device versus Auto-adjusting Positive Airway Pressure for Treatment of Positional Obstructive Sleep Apnea, Journal of Clinical Sleep Medicine, 2019 ,Vol. 5, No.7, 947-956

# The POSActive Study

## Results

Endpoint*	SPT	APAP
<b>AHI</b> (events/hr)	7.29 ± 6.8 (0.6-33.2)	3.71 ± 5.1 (0.2-31.6)
<b>Adherence</b> (avg. hrs, all nights)	5.8 ± 1.9 (0.4-9.1)	4.8 ± 2.1 (0.02-9.4)

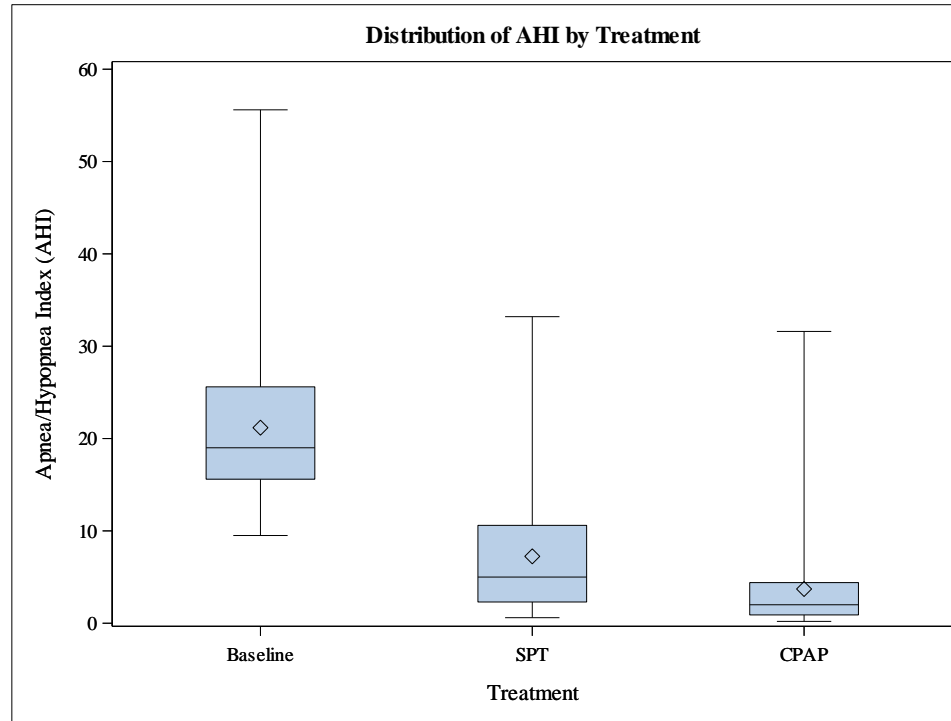
\*Mean +/- SD (min-max)

Primary Endpoint Analysis	Mean Difference	90% CI (Lower)	90% CI (Upper)	Outcome
<b>AHI</b> (events/hr)	<b>3.6</b>	2.2	4.9	<b>PASS</b>
<b>Adherence</b> (min)	<b>58.4</b>	36.6	81.2	<b>PASS</b>

Berry, Richard B. et al, NightBalance Sleep Position Treatment Device versus Auto-adjusting Positive Airway Pressure for Treatment of Positional Obstructive Sleep Apnea, Journal of Clinical Sleep Medicine, 2019 ,Vol. 5, No.7, 947-956

# The POSActive Study

## AHI

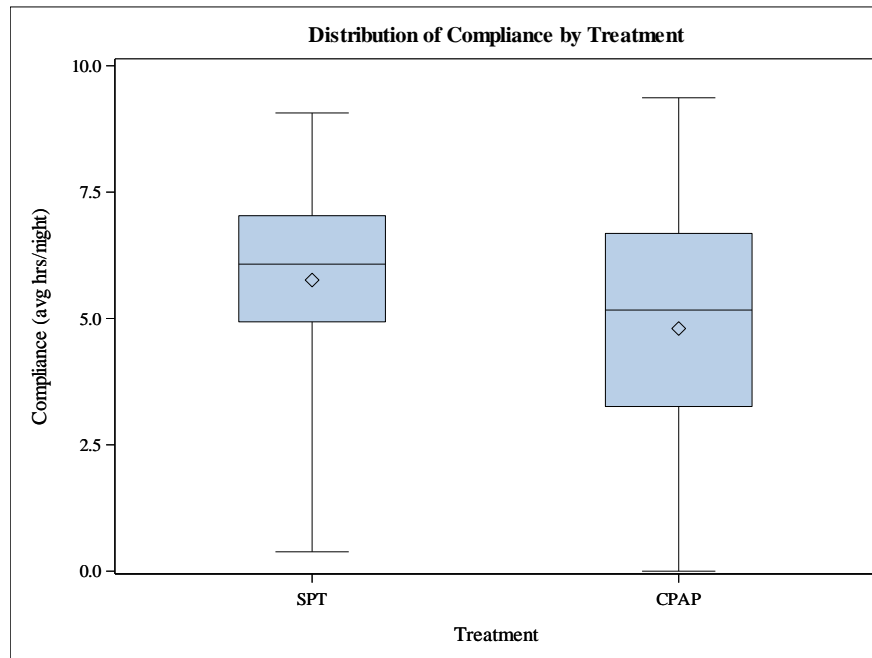


Endpoint	SPT	APAP
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Berry, Richard B. et al, NightBalance Sleep Position Treatment Device versus Auto-adjusting Positive Airway Pressure for Treatment of Positional Obstructive Sleep Apnea, Journal of Clinical Sleep Medicine, 2019, Vol. 5, No.7, 947-956

# The POSActive Study

## Adherence



Endpoint	SPT	APAP
Adherence (avg. hours used, all nights)	5.8 ± 1.9 (0.4-9.1)	4.8 ± 2.1 (0.02-9.4)

Berry, Richard B. et al, NightBalance Sleep Position Treatment Device versus Auto-adjusting Positive Airway Pressure for Treatment of Positional Obstructive Sleep Apnea, Journal of Clinical Sleep Medicine, 2019, Vol. 5, No.7, 947-956

# The POSAtive Study

- Other outcomes
  - Sleepiness was similarly improved on both the NightBalance and APAP devices
  - A greater proportion of POSA patients felt the NightBalance device was easier to use, easier to adjust to and more comfortable

# The POSAtive Study

- Conclusion

Treatment with SPT resulted in non-inferior treatment efficacy and greater adherence compared to APAP in POSA suggesting that SPT is an effective treatment for this group



Example of SPT

Berry, Richard B. et al, NightBalance Sleep Position Treatment Device versus Auto-adjusting Positive Airway Pressure for Treatment of Positional Obstructive Sleep Apnea, Journal of Clinical Sleep Medicine, 2019 ,Vol. 5, No.7, 947-956

# Case Study: Typical Patient

# Typical POSA Patient

- 49 year old male, BMI = 27.3, neck circumference 15.5”
- Clinical complaint:
  - Loud disruptive snoring
  - Subjective daytime sleepiness:
    - analogue rating “3” on a scale of 0-5
- PMH: asthma, reflux, ADD, tinnitus
- Recent weight gain 10-15 lbs

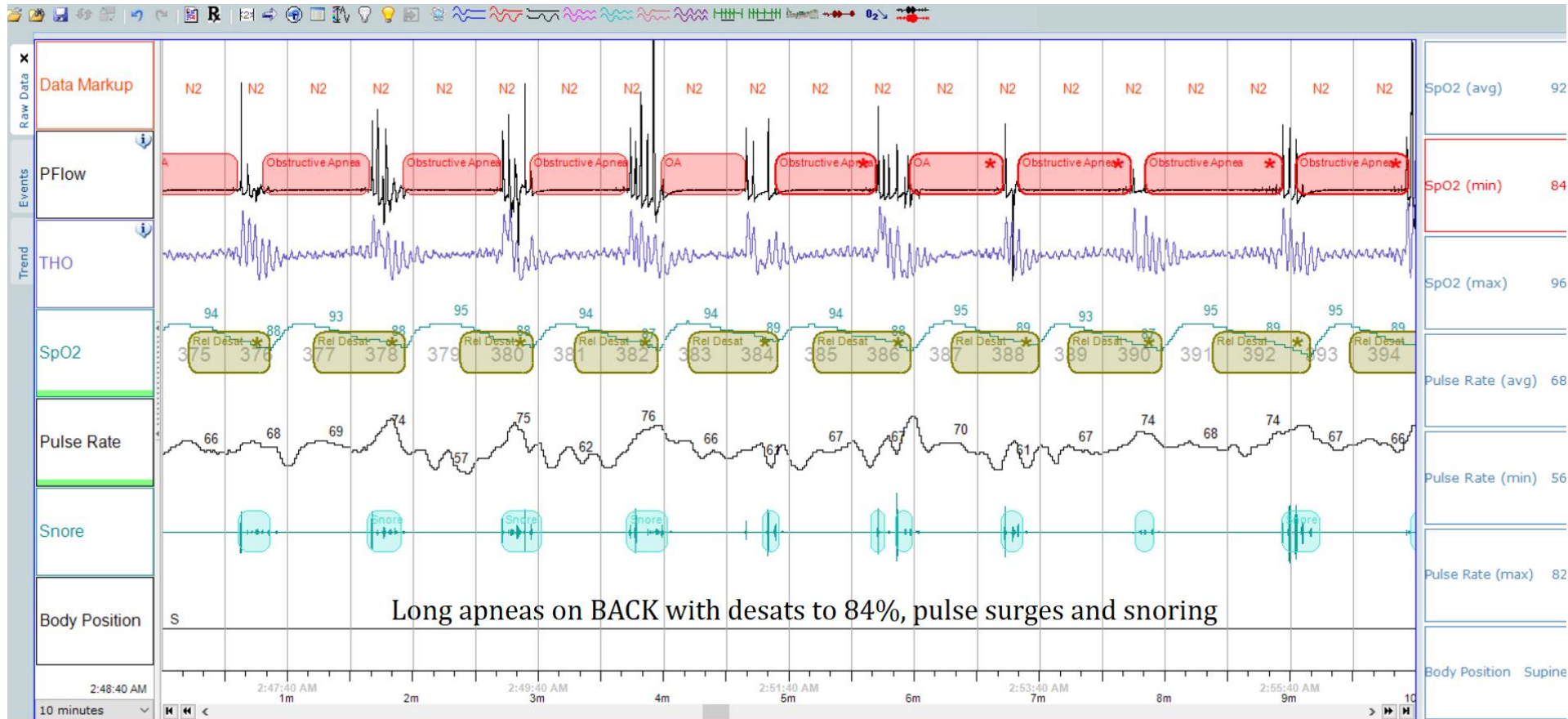
Times and Durations			
Lights off clock time:	11:48:22 PM	Total Recording Time (TRT):	439.9 minutes
Lights on clock time:	6:58:10 AM	Time In Bed (TIB):	429.8 minutes
		Quiet Valid Airflow Monitoring Time (MT):	423.5 minutes

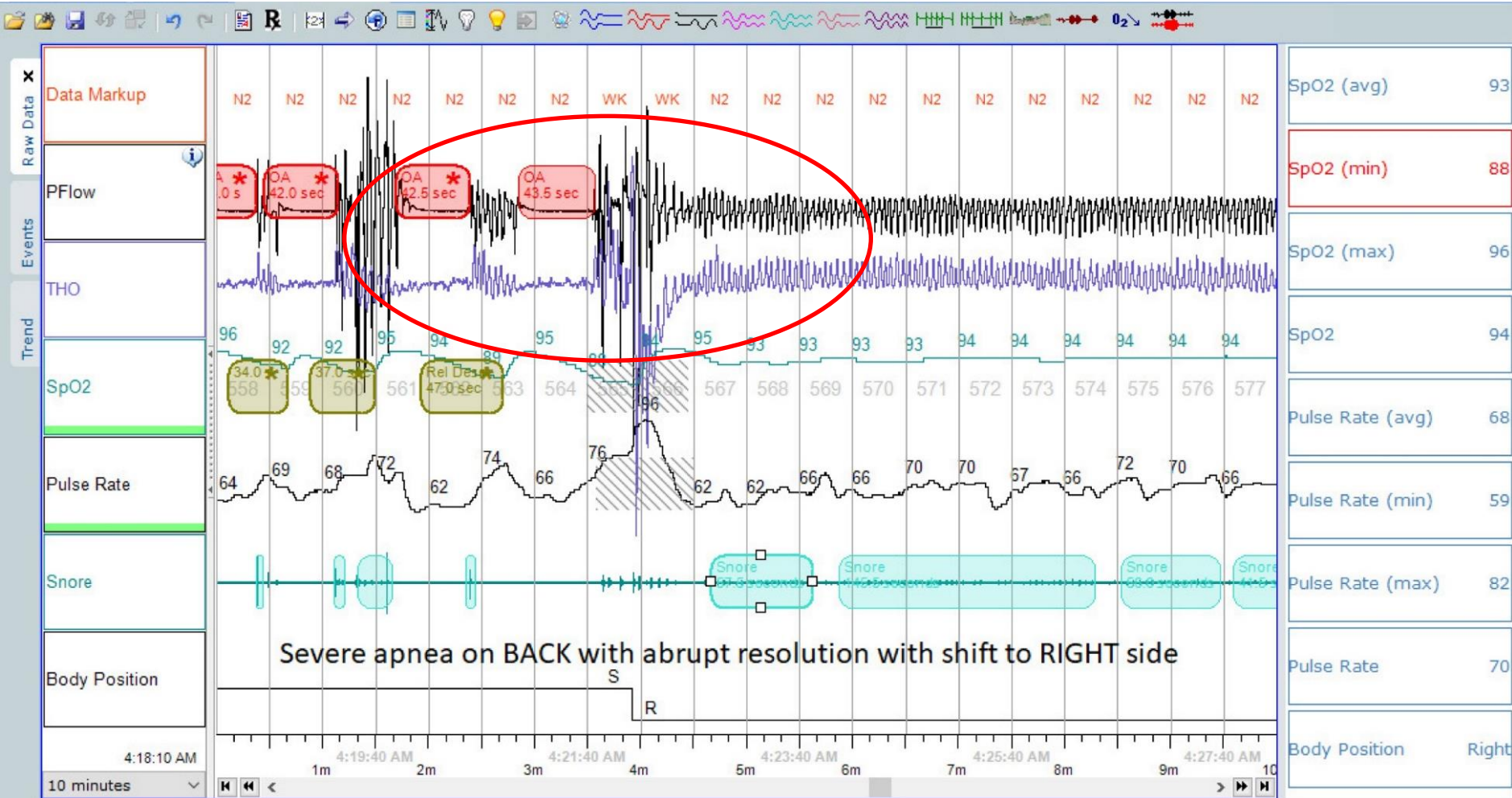
### Summary

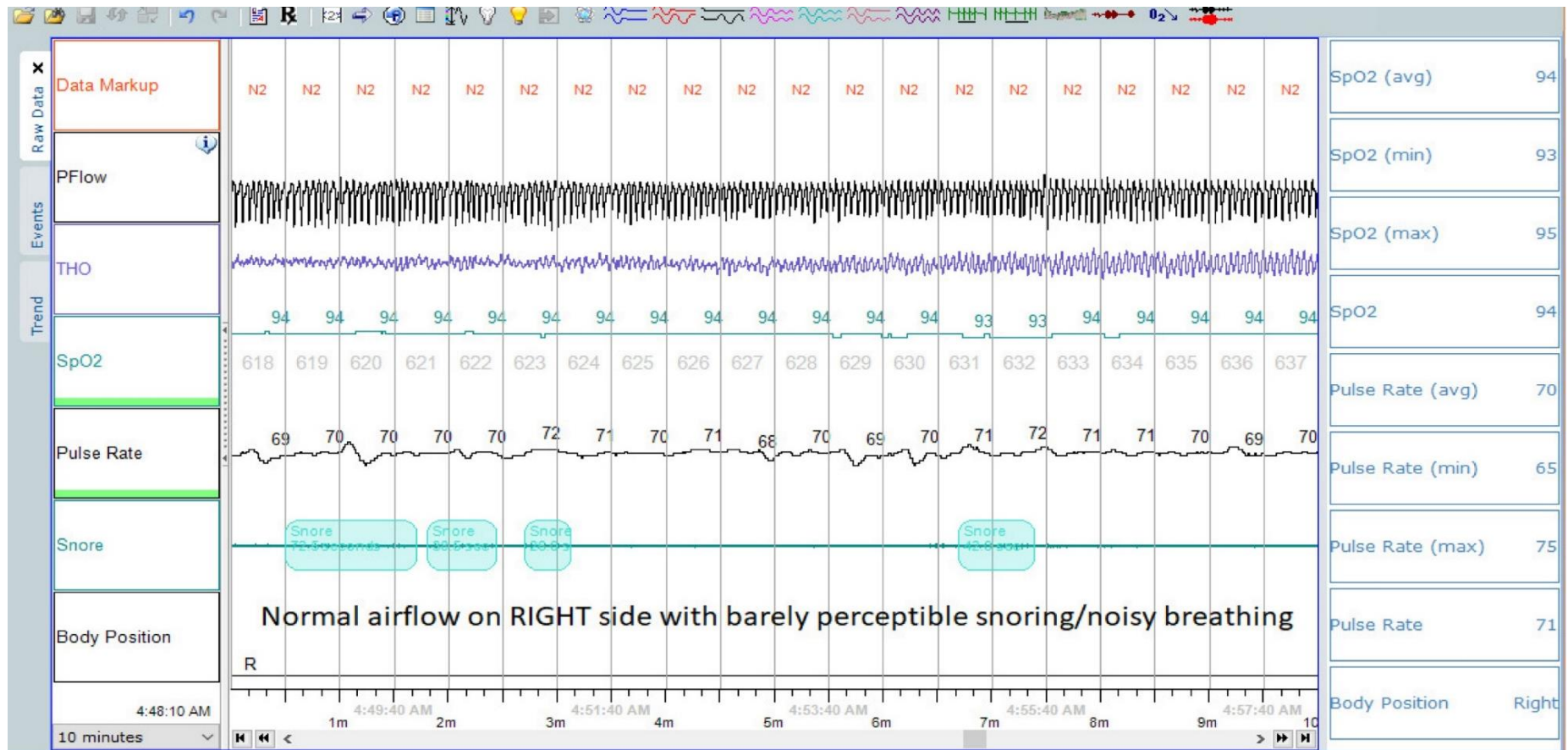
REI	<b>26.8</b>	OAI	<b>18.1</b>	CAI	<b>0.0</b>	Lowest Desat	<b>83</b>
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REI = the number of respiratory events per hour of monitoring time. This may overestimate the sleep time, thus the REI underestimates the traditional RDI and AHI. This portable methodology does not include an EEG channel to verify wake versus sleep time. Scored using the AASM 2012 3% hypopnea criteria (except Medicare, Tricare & United studies which are scored with the 2007 4% hypopnea rule). Pulse rate surge >6 beats per minute is used as a surrogate measure of arousal to assist in identification of RERAs (Respiratory Effort Related Arousals).

RESPIRATORY EVENTS									
	Index (#/hour)	Total # of Events	Mean duration (sec)	Max duration (sec)	# of Events by Position				
					Supine	Prone	Left	Right	Non-Supine
Central Apneas	0.0	0	0.0	0.0	0			0	0
Obstructive Apneas	18.1	128	35.4	68.0	128			0	0
Mixed Apneas	0.0	0	0.0	0.0	0			0	0
Hypopneas	3.7	26	28.7	67.0	22			4	4
Apneas + Hypopneas	21.8	154	34.2	68.0	150			4	4
RERAs	5.0	35	22.7	68.0	27			8	8
<b>Total</b>	<b>26.8</b>	<b>189</b>	32.1	68.0	177			12	12
Sleep time in Position					287.0			136.5	136.5
REI in Position					<b>37.0</b>			<b>5.3</b>	<b>5.3</b>







# Question 4

Question:

After today's presentation, I will consider specific devices treatment of POSA.

Answer:

Yes

No

# Questions



