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 1st described\textsuperscript{1}

In 1969

Tracheostomy to bypass the upper airway affected by OSA

In 1976

Scoring parameters for OSA are established

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\(^1\)

- 1984: Cartwright suggested interventions could keep patients off of their backs\(^2\)

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
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:

\[ \text{AHI}_{\text{supine}} \geq 2 \times \text{AHI}_{\text{non-supine}} \]

Positional Sleep Apnea (POSA)

POSA definition = AHI reduction of ≥ 50% from supine to non-supine position

AHI = 30 /hr

AHI ≤ 15 /hr

2x apnea on back

Cartwright, R. criteria, Effect of Sleep Position on Sleep Apnea Severity, R. Cartwright, Sleep 1984;7:110-114
Positional Sleep Apnea (POSA)

1. Sleeping on the Sides
   Unobstructed Breathing

2. Sleeping on the Back
   Snoring

3. Sleeping on the Back
   Partial Obstruction
   Collapsed Air
   OSAS
Exclusive Positional Sleep Apnea (ePOSA)

AHI = 20 /hr

AHI < 10/hr

Supine AHI >2x Non-supine AND Non-supine <10/hr

Cartwright, R. criteria, Effect of Sleep Position on Sleep Apnea Severity, R. Cartwright, Sleep 1984;7:110-114
Positional OSA Prevalence

• POSA prevalence in 74.1% of OSA patients
  – ePOSA was present in 36.1% of OSA subjects\(^1\)

• Main characteristics of Positional OSA population:
  - Lower AHI
  - Lower BMI with less abdominal obesity (men)

## Prevalence and determinants

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

POSA prevalence among OSA severities\textsuperscript{1}
Prevalence of POSA and ePOSA according to different AHI thresholds

- AHI ≥ 5/h: 74.6%
- AHI ≥ 15/h: 70.1%
- AHI ≥ 30/h: 60.4%
Prevalence of ePOSA according to sex and AHI thresholds

- AHI > 5
  - Men: 41.8%
  - Women: 31.4%

- AHI > 10
  - Men: 51.1%
  - Women: 51.9%

- AHI > 15
  - Men: 40.6%
  - Women: 51.9%
Question 3

Question: What is the definition of ePOSA?

Answer:

\[ \text{AHI}_{\text{supine}} \leq 2 \times \text{AHI}_{\text{non-supine}} \]

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

AHI reduction of > 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\(^1\) 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

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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

- Prescription use
- Adult population
- AHI supine ≥ 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

PHILIPS
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%\(^1,2\)

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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

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

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 2nd line therapy or supplement to primary therapy if low AH1 in the non-supine position

United States

Morgenthaler, T. et al, Practice Parameters for the Medical Therapy of Obstructive Sleep Apnea, Sleep, Vol 29, No 8, 2006
Clinical Validation

Clinical trial data published in 10 peer-reviewed medical journals

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;

Recent DeRuiter 12M Durability Publication
Original Article

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

Linda Benoist a, b, *, Maurits de Ruiter c, d, Jan de Lange c, d, Nico de Vries a, d, e

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b Department of Otorhinolaryngology and Head and Neck Surgery, Erasmus University Medical Center, Rotterdam, The Netherlands
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d Department of Oral Kinesiology, Amsterdam, The Netherlands
e 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 Ruiter¹ & Linda B. L. Benoist²,3 & Nico de Vries²,4,5 & Jan de Lange¹,4
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

The POSAtive 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 POSAtive Study

Methods

Screening and Baseline Assessments (N=187)

Device Training and Randomization (N=117)

1:1 Randomization of Treatment Order

N=59

N=58

6 Weeks of Home Use with APAP
- 6 Weeks of use with Follow-ups
- 6 Week Treatment PSG
- Repeat Assessments

6 Weeks of Home Use with SPT
- 6 Weeks of use with Follow-ups
- 6 Week Treatment PSG
- Repeat Assessments

5 Subjects Withdrew in the 1st 6 weeks:
- 3 Voluntary Decision (1 CPAP, 1 SPT)
- 1 Moved (Military, SPT)
- 1 Investigator Decision (non-compliance, CPAP)

2 Subjects Withdrew in the 2nd 6 weeks:
- 2 Voluntary Decision (1 CPAP, 1 SPT)

Study Completion (N=110)

# The POSAitive Study

## Demographics

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

*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

The POSAtive Study

Results

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

*Mean +/- SD (min-max)

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

The POSAtive Study

### AHI

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>SPT</th>
<th>APAP</th>
</tr>
</thead>
<tbody>
<tr>
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<td>7.29 ± 6.8 (0.6-33.2)</td>
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</tbody>
</table>

The POSAtive Study

Adherence

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>SPT</th>
<th>APAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adherence (avg. hours used, all nights)</td>
<td>5.8 ± 1.9 (0.4-9.1)</td>
<td>4.8 ± 2.1 (0.02-9.4)</td>
</tr>
</tbody>
</table>

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.

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

<table>
<thead>
<tr>
<th>Description</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lights off clock time:</td>
<td>11:48:22 PM</td>
</tr>
<tr>
<td>Lights on clock time:</td>
<td>6:58:10 AM</td>
</tr>
<tr>
<td>Total Recording Time (TRT):</td>
<td>439.9 minutes</td>
</tr>
<tr>
<td>Time In Bed (TIB):</td>
<td>429.8 minutes</td>
</tr>
<tr>
<td>Quiet Valid Airflow Monitoring Time (MT):</td>
<td>423.5 minutes</td>
</tr>
</tbody>
</table>

## Summary

<table>
<thead>
<tr>
<th>REI</th>
<th>OAI</th>
<th>CAI</th>
<th>Lowest Desat</th>
<th>83</th>
</tr>
</thead>
<tbody>
<tr>
<td>26.8</td>
<td>18.1</td>
<td>0.0</td>
<td>83</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Index (#/hour)</th>
<th>Total # of Events</th>
<th>Mean duration (sec)</th>
<th>Max duration (sec)</th>
<th>Supine</th>
<th>Prone</th>
<th>Left</th>
<th>Right</th>
<th>Non-Supine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Apneas</td>
<td>0.0</td>
<td>0</td>
<td>0.0</td>
<td>0.0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obstructive Apneas</td>
<td>18.1</td>
<td>128</td>
<td>35.4</td>
<td>68.0</td>
<td>128</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Mixed Apneas</td>
<td>0.0</td>
<td>0</td>
<td>0.0</td>
<td>0.0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Hypopneas</td>
<td>3.7</td>
<td>26</td>
<td>28.7</td>
<td>67.0</td>
<td>22</td>
<td>0</td>
<td>4</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Apneas + Hypopneas</td>
<td>21.8</td>
<td>154</td>
<td>34.2</td>
<td>68.0</td>
<td>150</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>RERAs</td>
<td>5.0</td>
<td>35</td>
<td>22.7</td>
<td>68.0</td>
<td>27</td>
<td>8</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>26.8</td>
<td>189</td>
<td>32.1</td>
<td>68.0</td>
<td>177</td>
<td>12</td>
<td>12</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sleep time in Position**

- Supine: 287.0 minutes
- Prone: 136.5 minutes
- Left: 136.5 minutes

**REI in Position**

- Supine: 37.0
- Prone: 5.3
- Left: 5.3
Long apneas on BACK with desats to 84%, pulse surges and snoring
Severe apnea on BACK with abrupt resolution with shift to RIGHT side
Normal airflow on RIGHT side with barely perceptible snoring/noisy breathing
Question 4

Question:

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

Answer:

Yes
No
Questions