What’s New in OSA Treatment; Looking Beyond CPAP Therapy

2017 Focus Spring Conference
Orlando, Fla
May 5th, 2017
Steven A. Thau MD
Conflicts:

- JP Morgan Chase Home Mortgage, HELOC
- Barnard College
- SUNY Binghamton
- SAR High school
- BCDS
- I have no conflicts that pertain to this talk but I’m willing to reconsider
Obstructive Sleep Apnea

Definition:
Repetitive episodes of upper airway obstruction (complete or partial) that occur during sleep and are associated with arousals or desaturations +/or daytime sleepiness. Results are reported as respiratory disturbance index or RDI

- 5-20 events/hour mild
- 20-40 events/hour moderate
- > 40 events/hour severe
The soft palate is the tissue at the back of the roof of your mouth. It helps block off your nose when you swallow.

The uvula is a long flap of tissue that hangs from your soft palate.

Tonsils are balls of tissue in the throat. They may play a small role in helping your body defend itself against illness.

The tongue helps you talk, chew, and swallow.

Normally, air flows freely past the structures in the throat.
During snoring, air flow is partially blocked.

During sleep apnea, air flow is completely blocked.
Cardiovascular Effects of OSA

- Negative intrathoracic pressure
  - Increased preload and afterload
  - Reduced Stroke Volume
- Hypoxemia and hypercapnia
  - Increased resp. drive & sympathetic tone
- Pulmonary vasoconstriction
- Systemic vasoconstriction
- Cardiac arrhythmias
Cardiovascular Effects of OSA

Post Apnea

- Increased sympathetic tone
- Increased heart rate
- Increased blood pressure

Repetitive Mueller maneuvers complicated by hypoxemia, hypercapnia, pulmonary vasoconstriction result in systemic hypertension and sleep deprivation.
Morbidity of OSA

- Cardiac Arrhythmia/MI
- Systemic Hypertension
- Pulmonary Hypertension
- Sleep Fragmentation
- Impaired QOL
- Increased Mortality - both cardiac and MVA’s (from decreased reaction time = DWI)
Epidemiology of OSA
Young, et. al. 1993

Graph showing prevalence of different conditions:
- HTN
- RA
- Insomnia
- W RDI>5

Prevalence % along the y-axis.
Prospective Studies

- **Nurses Health Study**
  - Began in 1976, 121,700 nurses ages 30-35
  - RR of HTN and CVD 1.6 and 1.3 respectively for the snorer vs nonsnorer
  - Adjusted for numerous confounders

- **Wisconsin Sleep Cohort Study**
  - 5000 WI state employees, age 30-60 8yr f/u
  - Logistic OR 1.8,3.0 for HTN if RDI 15,30
  - OR for CVD=3.0 if RDI>30
Sleep Heart Health Study

- N=6132 with 5 yr f/u PSG
- RDI>30, OR 1.5 for HTN
- Participants from several cardiovascular cohorts
- Adjusted for age, gender, BMI, race, smoking
CPAP

- The most effective treatment.
- Treats mild, moderate and severe OSA.
- >90% of patients will improve with CPAP during the first night of use.
- Long term compliance is 60-80%.
- Compliance is associated with education and perceived daytime sleepiness.
Representing the effect of CPAP on the upper airway in obstructive sleep apnea syndrome. The first panel shows the development of negative inspiratory pressure; muscle tone is required to prevent collapse of the upper airway. The second panel shows collapse when the inspiratory negative pressure exceeds the counteracting muscle tone that maintains airway patency. The third panel shows the application of positive airway pressure through the nares which overcomes the negative inspiratory pressure and improves airway patency.
With CPAP, a mask over your nose gently blows air into your throat to keep your air passage open.
CPAP: Pros & Cons

- Effective for all severities of OSA.
- Excellent data to support reversal of the cardiovascular, cognitive and metabolic sequelae.
- Cost effective, covered by insurance.
- Easy to start, easy to stop.

- Difficult for some to find a comfortable mask, pressure setting or mode.
- Needs to be worn on a nightly basis.
- Unattractive, unappealing and intrusive in the bedroom.
- Requires expertise for some (Laura!) not widely available in many parts of the country.
Anatomy of Obstructive Sleep Apnea

- Nasal congestion
- Enlarged Uvula
- Large Tongue
- Enlarged tonsils
- Redundant soft tissue
- Jaw Structure
Oral Appliances
Provent
Provent- Pro/Con

- Highly transportable
- No battery required
- Small lightweight, no tubing, bulky mask/device over the face.
- Easy to start/stop
- An ongoing expense
- Requires nightly reinsertion
- Requires acclimitization
- Limits to the protection that it can afford.
- Need special cannula for O2 use
Inspire

- May have heard commercials about this.
- Has an implanted battery/generator under the skin.
- Breathing sensor in the chest.
- Stimulation lead in the neck to stimulate the hypoglossal nerve (CN XII) to move the tongue forward.
- Remote control turns the device on when in bed ready for sleep.
Inspire

**Stimulation Lead**
Delivers mild stimulation to maintain multilevel airway patency during sleep

**Generator**
Monitors breathing patterns

**Breathing Sensor Lead**
Senses breathing patterns
How Does Inspire Therapy Work?

Untreated sleep apnea patient

Tongue and other soft tissues relax and block the airway

Patient with Inspire therapy

Mild stimulation to key airway muscles maintains an open airway
Inspire: Advantages

- Less invasive (by A LOT!) than conventional OSA surgeries.
- Remote device keeps battery life longer. (10 years)
- Inserted in a 2 hour outpatient procedure, 1x 2 inch and 2x 1 inch incision. Pain Rx’ed OTC pain meds PRN for swelling.
- Return to regular diet and activity quickly.
- Great for people who travel, they have to take the neck with them! Do take an ID card shown to TSA but no CPAP to take with you.
- FDA approved, Covered by insurance (with PA) including the VA’s!
- Easy to remove. Unlike other ENT surgeries, reversible!
- Prior ENT surgery not a contraindication.
- No change in speech, swallowing or dental work. There is rubbing but decreased with adjusting the stimulation.
Inspire Therapy Performance
The STAR Clinical Trial
Results published in the New England Journal of Medicine

Results at 1 year:
- 86% of patients reported using the therapy every night
- On average, patients experienced a 70% decrease in their sleep apnea events
- 85% of patients showed improvement in their quality of life measures
- 85% of bed partners reported “no or soft snoring”

There were no unanticipated adverse events — only two events required surgical intervention. Both involved repositioning the generator — procedures performed under local anesthesia.

Sources:
- Inspire STAR clinical database
What’s New in OSA Treatment; Looking Beyond CPAP Therapy

Focus Fall 2016 Conference; The 35th Annual Michael Aeillo Resp Care and Sleep Medicine Conference
October 27th, 2016
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Air flow
Soft palate
Base of the tongue
Uvula
Tonsils

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CPAP
**CPAP and EF**

Naughton et al’95 studied 35 patients with EF~23% +/- one month of CPAP

<table>
<thead>
<tr>
<th></th>
<th>NO CPAP</th>
<th>CPAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>U Norepi (nmol/mmol creat)</td>
<td>31</td>
<td>18</td>
</tr>
<tr>
<td>Plasma Norepi (nmol/L)</td>
<td>3.2</td>
<td>2.4</td>
</tr>
</tbody>
</table>

Tkacova et al’97 studied 17 patients with EF~23% before and after 3 months of treatment with CPAP

<table>
<thead>
<tr>
<th></th>
<th>NO CPAP</th>
<th>CPAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>EF</td>
<td>21%</td>
<td>28%</td>
</tr>
<tr>
<td>Pl Atrial Naturetic Factor</td>
<td>141</td>
<td>104 pg/ml</td>
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Becker et al Circ ’03

Investigated the role of CPAP on blood pressure.

Methods: 32 patients with OSA randomized to therapeutic CPAP or subtherapeutic CPAP for ~ 9 weeks. Patient did not have to have HTN.
Becker et al Circ ’03
Investigated the effects of CPAP treatment for OSA on cardiac function.

**Methods:** 32 patients with OSA and heart failure (avg EF ~ 27%) randomized to therapeutic CPAP or best medical management for ~ one month.

*The patients did not have to be sleepy.*
<table>
<thead>
<tr>
<th>Variable</th>
<th>Control Group</th>
<th></th>
<th>Group Receiving Continuous Positive Airway Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Base Line</td>
<td>1 Mo</td>
<td>Base Line</td>
</tr>
<tr>
<td>Heart rate (beats/min)</td>
<td>67±4</td>
<td>67±4</td>
<td>68±3</td>
</tr>
<tr>
<td>Systolic blood pressure (mm Hg)</td>
<td>128±7</td>
<td>134±8</td>
<td>126±6</td>
</tr>
<tr>
<td>Diastolic blood pressure (mm Hg)</td>
<td>60±4</td>
<td>58±3</td>
<td>62±4</td>
</tr>
</tbody>
</table>

* NS denotes not significant. Plus–minus values are means ±SE. There were no significant differences in base-line values between the control group and the group given continuous positive airway pressure. Unless otherwise specified, P values are for the comparisons between base-line values and one-month values within the group.

† P=0.09 for the comparison between the groups.
‡ P=0.008 for the comparison between the groups.
Kaneko et al NEJM ’03

Graph showing changes in left ventricular ejection fraction from baseline to 1 month for the control group and the group treated with continuous positive airway pressure. The control group shows no significant change (P=0.09), while the treated group shows a significant increase (P<0.001).
SUMMARY

- Epidemiologic data to support an association between OSA and CVD.
- Physiologic data that demonstrates a link.
- Positive pressure has been used in ICU’s for years to treat patients with CHF.
- Now more comfortable non-invasive modality for “stable” outpatients.
SUMMARY

- Good data to support treatment reverses negative effects.
- Relatively inexpensive when compared with other modalities. (All the benefits of a beta-blocker without the impotence! In fact, improves libido.)
- Need to ask the questions! Won’t recognize OSA unless you do. (~ guessing BP)
  - DO YOU SNORE?
  - IS YOUR SLEEP REFRESHING?
CONCLUSION

- Sleep disturbances have huge medical implications.
- Snoring, although common, is ABNORMAL and should be investigated further!
- Problem getting worse due to obesity.
Inspire: What to tell patients

- Most patients describe it as a muscle twitch or tingling sensation.
- There is a 30 min delay to allow people to fall asleep.
- Most patients get used to it in the 1st week.
- Adjustable degree of amplitude of stimulation for comfort.
- Will need repeat study to document effectiveness.
- Serious complications rare.
- Working on MRI compatible device. Not yet avail
- No interference with bluetooth, cell phone, microwave (off during the day anyway!)
Inspire: Caveats

- Only for CPAP failures
- AHI 20-65 and <25% CA
- Older than 22
- Do not have concentric collapse. (need endoscopic eval usually under sedation)
- Not been tested in patients with BMI>32.
- Does require GA. (severe cardiac, resp disorder)
- Not yet MRI compatible
What If...There was a way to move the tongue forward without surgery?

- And without a device that would change your bite.
- Or cause TMJ
- Or loosen dental work?
Winx® Sleep Therapy System

- A new treatment option for mild, moderate, and severe OSA
- Designed to increase treatment adherence and overall efficacy without the inconvenience of a mask.
- Uses a proprietary technology called Oral Pressure Therapy (OPT). OPT provides light negative pressure to the oral cavity, increasing the size of the retropalatal airway by pulling the soft palate forward and stabilizing the base of the tongue. OPT increases the airway in both the anterior-posterior and lateral dimensions.
Winx® Sleep Therapy System
Console
Compact, discreet, quiet, travel friendly, easy to clean, stores patient usage data

Tubing
Slim, flexible, soft, offers mobility

Mouthpiece
Soft and flexible
Winx® Sleep Therapy System

- OSA Therapy without a mask
- Quiet console
- Slim tubing for sleeping in any position
- Soft, flexible mouthpiece
- Easy to use, clean and maintain
- Compact and travel friendly
ATLAST Study

- ATLAST multicenter, prospective, clinical trial was conducted to determine the safety and effectiveness of the Winx System for the treatment of OSA. Study results demonstrated significant improvements in AHI and ODI for patients with moderate and severe OSA. Treatment was durable over 28 days, and adherence was high, with strong patient and bed partner satisfaction.

- Responders were easily identified, and achieved median AHI reduction from 26.2 to 5.7.

- Median objectively recorded usage per night was 6.0 hours.

- 76% of participants responded they would use the Winx System to treat their OSA.

- European Sleep Research Society, JSR 21 (Suppl. 1);2012:P697
Winx® Sleep Therapy System: Data

- SLEEP 2014;37(7):1237-1247
- Am J Respir Crit Care Med 185;2012:A6811
- European Sleep Research Society, JSR 21 (Suppl. 1);2012:O310
Winx® Sleep Therapy System: Caveats

- Need to be able to breathe through your nose with your mouth closed.
- Assessment of effectiveness should be conducted to ensure adequate treatment effect.
- BMI < 40
- Oral discomfort, dental discomfort, and dry mouth were common events which resolved quickly in some patients and persisted for longer periods in others.
Winx® Sleep Therapy System: Caveats

- Using a therapeutic success definition of at least a 50% decrement in AHI and a treated AHI of < 10 events per hour, 20 of the 63 patients (31.7%) were successfully treated.
- If a final AHI of < 20 events per hour was used, 26 of the 63 patients (41.3%) were treated successfully. Successful results with this device were not related to initial AHI or BMI.
- For the group not treated with CPAP at the beginning of the trial, the ESS fell from 12.1 to 8.6.
- Cost of the console between $600 to 1,000 depending on the payer and the mouthpiece (which needs to be replaced every 3–6 months) costs about $100 -$120
The Silent Treatment

- Different take on the oral appliance and tongue advancement. “Control the tongue, control the snoring”
- More of a tongue “trainer” than an advancement device without TMJ or dental issues.
- The papilla of the tongue assist to keep the tongue forward.
- Designed with hundreds of tiny spurs on the underside which are shaped, sized and spaced to precisely mesh with the hundreds of papilla that cover the upper surface of the tongue. Think of the device and your tongue as Velcro.
The Silent Treatment

- Also holds the tongue in position and prevents it from drifting back and blocking the airway while sleeping.
- A separate part of the device holds the lower jaw in its correct and natural position, relative to the upper jaw.
- Because the tongue is attached to the lower jaw, these two separate actions combine to achieve complete control over the tongue position without either action needing to be so forceful as to cause discomfort or harm.
The Silent Treatment

- "Muscle Memory" will kick in, meaning that the tongue will 'remember' the forward, flattened position it has been staying in during sleep.

- This means that you are effectively "training" your tongue, and you will be able to go for several nights without needing to use your Silent Treatment.

- From there it only takes a few hours of use once a week or so to keep the memory active.
The Silent Treatment

Fitting Instructions

Thank you for purchasing this product.

Caution: A poorly fitted ST (Silent Treatment) may result in reduced effectiveness and/or comfort.

Set a pot of water to boil. Examine your ST. It has a channel shaped control body with hundreds of tiny spurs on the underside. The channel walls are higher at the front. At each side is a bulb made of a special low melting point plastic. You are going to bite these bulbs until they fit snugly around your teeth.
The Silent Treatment

- Cheap!!! Only $62!!
- Lasts for years with proper care.
- Boil, then bite.
- Helps with bruxism as well.
- Works even with mouth breathers.
On the Postional Therapy Front: Night Shift

- Worn on the back of the neck, Night Shift begins to vibrate when users begin to sleep on their back and slowly increases in intensity until a position change occurs.

- “First line therapy” for positional OSA; in combination with CPAP (may lower CPAP pressure), oral appliance therapy, surgery, or Provent to improve outcomes.

- Decreases the # of arousals in patients with POSA. The # of arousals due to sleep disorder breathing exceeded the number of supine attempts resulting in positional feedback by a factor of 15.

- Use of Night Shift resulted in significant reductions in stage N1 and increased in N2, while REM and sleep efficiency increase and arousals and awakenings were significantly reduced.
Night Shift
Night Shift

- **Appropriate AHI**: positional mild, moderate, or severe OSA when nonsupine AHI <20

- Has compliance monitoring capability (tennis balls and bumper belts don’t!). Important for CDL’s etc.

- Positional therapy can reduce the overall AHI to the nonsupine severity, its effect on snoring is more variable since in patients with an elevated supine apnea index, overall snoring may increase with positional therapy because supine apneas are replaced with snoring.

- Also, to avoid long-term complications from side sleeping, patients should select a pillow(s) that align the head with the spine during lateral sleep and/or allow the cervical and thoracic spine to be as horizontal as possible during prone sleep.
Night Shift; Caveats

- Not for those with acute neck, shoulder, or back pain, cardiac arrhythmia corrected with an artificial pacemaker, or who have skin sensitivity or an open wound around the neck.

- AHI non-supine <20.

- Am I the only one who thinks it looks like a dog collar? But then again people are buying ripped jeans and paying more for them so what do I know?!
What If…We Make a Hoseless, Cordless, Maskless, Battery-powered CPAP device?

- Airing.
- A micro CPAP device (or mini-blowers) capable of generating pressures of 1-20cm.
- Easy one-hand insertion with little need for adjustment.
- Available in a range of sizes to accommodate different nostril shapes.
- Available initially in a pressure range so that you obtain the device with the treatment number prescribed for you, much CPAP.
- Eventually, the plan is to make the devices adaptive so that they will self adjust (like APAP machines) to provide the exact pressure for effective treatment.
Airing

- Does not require active humidification.
- Built-in pressure sensing and will be able to adjust the micro-blower output instantaneously.
- This ability to respond to where a person is in the breathing cycle eliminates the need for excessive air flow.
- This allows more natural breathing and mitigates or may even eliminate the need for additive active humidification.
- Passive humidification is possible if desired.
Airing

- **Cost** - $3 per Airing device, or $0.60 after insurance reimbursement.

- The invention of the micro-blowers is the technological breakthrough at the heart of the Airing micro-CPAP device. The power source is based on a similar technology Polaroid used in their film packs because it is powerful, mass manufacturable and inexpensive. The integrated electronics are analogous to those in the Kodak disposable cameras. (small, mass manufacturable and inexpensive). The rest of the device is low cost rubber and plastic. Each component is small, inexpensive and integrated, so the aggregate result is a very small, highly efficient, tightly integrated device.
The integrated pressure sensors and electronics that control the Airing device are able to track the patient’s breathing cycle and deliver the proper treatment.

The appropriate data can be stored for subsequent retrieval.

This built in feature can be used for proof of compliance that will help with reimbursements.

Provides 8 hours of treatment before the energy in the battery is consumed.

Not yet FDA approved but likely short tracked since not a truly new modality.
In normal circumstances, the default position of the mouth is closed. When nose breathing is diminished or obstructed, nature provides a backup: mouth breathing. But mouth breathing can cause snoring and dryness. Improving nose breathing will significantly reduce or eliminate mouth breathing. The nose buds of the Airing device are molded from a soft and pliable silicon rubber material. Their shape provides a gentle and flexible seal with minimum exposure to the surface of the nasal pathways. The comfortable nose buds even had a beneficial side effect of slightly opening the nasal pathways which itself aided correct breathing, so not a contraindication. The Zinc-air battery provides the best power per weight and volume, ease of manufacturing, cost, and environmental impact.
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- Positive pressure has been used for years to treat patients with OSA.
- Good data to support treatment - reverses negative effects.
- Relatively inexpensive when compared with other modalities. (All the benefits of a beta-blocker without the impotence! In fact, improves libido.)
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- Compliance is an issue.
- Now more comfortable non-invasive modalities for “stable” outpatients.
- Inspire, Winx, The Silent Treatment and Airing
- Still need to ask the questions! Won’t recognize OSA unless you do. (~ guessing BP)
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- Snoring, although common, is ABNORMAL and should be investigated further!
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- Need to expand our treatment options.
BREATHE EASY AND LOVE YOUR RT!
Thank You

Any questions?