Medical Therapy for OSA

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• Research support
  – Inspire Medical Systems

• Industry advisory
  – Inspire Medical Systems
  – Philips-Respironics
Overview

• Introduction
• Primary treatment options
  – Positive pressure therapy
  – Oral appliance therapy
  – Weight loss
• Adjunctive and new/emerging treatment options
Overview

- Common: 12-18 million in US
- Costly: 2x health care costs compared to controls (extra $3.4 billion/year)
- Upper airway that is too narrow and too collapsible
- Repetitive upper airway obstruction during sleep that impacts:
  - Sleep, daytime function, quality of life
  - Cardiovascular risk, health, longevity


Why does your patient have OSA?

**Complex/multifactorial...**

- **Anatomical**
  - Craniofacial structure
  - Pharyngeal anatomy
  - Nose
  - Obesity
  - Airway edema
  - Surface tension
  - Lung volume

- **Neuromuscular**
  - Pharyngeal sensation
  - Central respiratory motor output
  - Tonic activity of upper airway dilator muscles
  - Arousal threshold
  - Loop gain

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Why do we treat sleep apnea?

1. Improve symptoms/quality of life

2. Reduce the cardiovascular/health risks
Impact on Sleep, Daytime Function, and Quality of Life:

- Snoring
- Frequent awakenings at night
- Frequent urination at night
- Unrefreshing sleep
- Morning headaches
- Memory loss
- Focus/attention/concentration problems
- Irritability
- Daytime sleepiness
  - 7x increased risk of MVA
  - Workplace errors

Impact on Health, CV Risk, Longevity:

- GERD
- Obesity/weight gain
- Immune dysfunction
- HTN
- CAD
- Afib
- MI
- CVA
- Mortality


Overview

• Introduction
• Primary treatment options
  1. Positive pressure therapy
  2. Oral appliance therapy
  3. Weight loss
• Adjunctive and new/emerging treatment options
OSA Treatment Options

- CPAP/BIPAP
- Oral appliance
- Surgery
  - Nasal
  - Pharyngeal
  - Skeletal
- Weight loss
- Adjunctive measures:
  - Positional therapy
  - Smoking cessation
  - Orthodontics
- New / emerging:
  - Hypoglossal nerve stimulation
  - Provent
  - Winx
1) Positive pressure therapy

- Types
- Interfaces
- Titration methods

- Effectiveness
- Adherence
- Side effects
Positive pressure therapy

• **Types**
  – CPAP - Continuous
  – BIPAP - Bilevel
  – APAP - Autotitrating

• **Interfaces**
  – Nasal mask
  – Nasal pillows
  – Full face mask

• **Titration methods**
  – Full night in-lab titration PSG
  – Split-night PSG
  – Home APAP titration

Kushida CA et al. Practice parameters for the use of continuous and bilevel positive airway pressure devices to treat adult patients with sleep-related breathing disorders. *Sleep 2006; 29:375-80.*
CPAP: Effectiveness

- ↓ Snoring, nocturnal awakenings, nocturia, ESS, motor vehicle accidents
- ↓ CV events, cardiac arrhythmias, heart failure, blood pressure
- ↑ Neurocognitive function, QOL measures

CPAP: Adherence

- CPAP is an effective first-line therapy for OSA patients who use it consistently
- Results intimately tied to usage or ‘adherence’
- Minimum adherence definition: 70% nights, 4h/night.
- CPAP adherence rates
  - APPLES Study (2012): 39% CPAP adherence at 6-months
  - Home PAP Study (2012): 39% (Lab) and 50% (Home) CPAP adherence at 3 months
- Many factors limit adherence

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1Kushida CA et al. Effects of CPAP on neurocognitive function in OSA patients: the APPLES. Sleep 2012;36:1593-1602.


PAP adherence

• Minimum/optimum use unknown and likely variable
• ↑ usage → ↑ benefits

• Data download monitoring considered standard to:
  1. Confirm effectiveness and adherence
  2. Evaluate suboptimal response
     • ? inadequate usage
     • ? mask leak
     • ? insufficient pressure
     • ? failure to recognize and treat coexisting sleep disorder

• Long-term adherence/results may be improved by:
  – Education and patient support
  – Close clinical follow-up
  – Upper airway surgery

Weaver TE et al. Relationship between hours of CPAP use and achieving normal levels of sleepiness and daily functioning. *Sleep* 2007;30:711-9.

# PAP side effects

<table>
<thead>
<tr>
<th>Side effects</th>
<th>Management strategies</th>
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<tbody>
<tr>
<td><strong>Pressure or airflow related</strong></td>
<td></td>
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<tr>
<td><strong>Device or interface related</strong></td>
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<td><strong>Psychological reasons</strong></td>
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</table>
Positive pressure therapy (CPAP)
2) Oral appliance therapy

- **Types**
  - MRA/MAD
  - TRD
  - Thermoplastic

Oral Appliance Therapy

- **Mechanism of action**
  - Palate/lateral wall >> tongue/epiglottis
  - Cephalometric view
  - DISE view


Oral appliance therapy

• **Effectiveness**
  – 2006 AASM review
  – 52% had AHI <10
  – ↓ snoring, ESS
  – ↓ HTN
  – Sig heterogeneity in studies

• **Proper patient selection** and phenotyping may increase success rates
  – Positional OSA
  – BMI
  – Nose
  – DISE?

• **Oral appliance indications**
  (2006 AASM practice parameters)
  – Mild-moderate OSA patients who prefer them to CPAP or who do not respond to, are not appropriate candidates for, or who fail treatment attempts with CPAP.
  – Severe OSA if CPAP intolerant

• **Follow-up**
  – Sleep physician and dentist to assess subjective results and adherence
  – Sleep study to assess objective results


Ferguson KA et al. Oral appliances for snoring and obstructive sleep apnea: a review. *Sleep* 2006; 29;244-62.

Oral appliance therapy

• **Adherence**
  - Subjective report
  - Median use 77% nights 1st year
  - Adherence rates decrease with time: 56-68% by year 3
  - Similar to CPAP

• **Side effects**
  - Minor/common/temporary (do not affect long-term use or morbidity)
    - Pain – tooth, TMJ, headache
    - Excessive salivation
    - Dry mouth
    - Gum irritation
    - Morning-after occlusal changes
  - Severe/persistent (often lead to device discontinuation)
    - TMJ dysfunction
    - Tooth movement
    - Changes in occlusion

Ferguson KA et al. Oral appliances for snoring and obstructive sleep apnea: a review. *Sleep* 2006; 29;244-62.


3) Weight loss

- Increase in BMI → Increase in OSA prevalence
- 10% weight gain:
  - 6-fold increased risk of mod-sev OSA
  - 32% increase in the AHI
- 10% weight loss:
  - 26% reduction in AHI
- Bariatric surgery literature
  - 75% reduction in AHI


Obesity and obstructive sleep apnoea: mechanisms for increased collapsibility of the passive pharyngeal airway. *Respirology* 2012; 17:32-42.

Overview

- Introduction
- Primary treatment options
- Adjunctive and new/emerging treatment options
  - Behavioral modifications
  - Positional therapy
  - Lowering nasal resistance
  - Treatment of comorbid sleep conditions
  - New/emerging options
    - Hypoglossal nerve stimulation therapy (Inspire)
    - Nasal PEEP (Provent)
    - Intraoral negative pressure (Winx)
    - Oropharyngeal physical therapy
Behavioral modifications

• Sleep deprivation
  – Exact mechanism unclear: attenuates the hypercapnic ventilatory response?
  – Sleep quality and quantity impacted by caffeine, alcohol, stress, sleep environment, shift work, and other sleep/medical conditions
  – Counseling on proper sleep hygiene/duration may improve patient satisfaction and overall treatment outcomes

• Alcohol
  – ↑AHI
  – Additive effects of OSA and alcohol on neurocognitive function and driving risk

• Smoking
  – Independent risk factor (4-5x) for mod-sev OSA
  – Mechanism?: mucosal edema, blunted upper airway sensory feedback, LPR, cardiopulmonary disease


Positional Therapy

- **Zzoma Pillow**


- **NightBalance Sleep Position Trainer**

- **Cervical pillow**


Positional Therapy - Summary

Advantages/Benefits

- Low morbidity
- Inexpensive
- Useful adjunct to other medical/surgical therapy
  - HOB elevation to lower nasal resistance and facilitate nasal CPAP
  - Side positioning to augment surgical results
  - Neck extension to augment oral appliance effectiveness

Disadvantages/Limitations

- Various definitions
- Limited evidence for use as sole treatment option
  - Select cases only
  - F/U sleep testing
- Limited ability to monitor use/results over time
- Long-term adherence rates?
- Which phenotypes respond to positional therapy?
Lowering nasal resistance: Medical Tx

- Nasal steroid spray improved nasal congestion, subjective sleep quality, and daytime sleepiness\(^1\)
- Nasal antihistamine spray improved subjective sleep quality but not nasal congestion or daytime sleepiness\(^2\)
- Pediatric patients with allergic rhinitis and OSA: Nasal steroids improved AHI from 10.7 to 5.8\(^3\)


In OSA patients with symptomatic nasal obstruction, treating the nose can significantly improve the following, independent of AHI:

- Snoring\(^1\)
- Sleep architecture\(^2\)
- Subjective sleep quality (PSQI)\(^3\)
- Daytime sleepiness\(^2\) (ESS 10.6 → 4.5)
- Disease-specific and general-health QOL\(^4\)
- CPAP results\(^5\)
- Oral appliance results\(^6\)


Nose - Summary

• Nasal obstruction:
  – Independent contributor to sleep-disordered breathing
  – Negative predictor of success with CPAP or OAT

• Nasal airway essential to success with any form of OSA therapy

• Lowering nasal resistance (medically or surgically):
  – Improves subjective sleep outcomes
  – Improves results and adherence with medical device therapy

• Ask about the nose!
  – SNQ?
  – NOSE score?

Treatment of comorbid sleep conditions

- 1/3 of OSA patients in a sleep clinic have another sleep disorder


New/emerging options: Hypoglossal nerve stimulation therapy
Hypoglossal nerve stimulation therapy

Therapy Titration

No Stimulation

Stimulation Active
Prospective multicenter trial
- Moderate-severe OSA
- CPAP intolerance
- BMI ≤ 32
- Sedated endoscopy (DISE)

Subjects were followed for at least 12 months to assess efficacy and adverse events

Randomized therapy withdrawal arm at 12 months

Primary Outcome Measures (n = 124)

68% reduction in AHI from baseline to Month-12

70% reduction in ODI from baseline to Month-12

2/3 of patients were ‘responders’: AHI 30 → 6

Secondary Outcome Measures (n = 123)

ESS

Baseline Month - 12

ESS

Baseline Month - 12

p < 0.0001

FOSQ

Baseline Month - 12

p < 0.0001

Multilevel effect during sedated endoscopy

Reference: 2 slices
New/emerging options: Provent

- Provent (Theravent)
- Nasal expiratory pressure device


New/emerging options: Winx

- Winx (Apnicure)
- Intraoral negative pressure

Oropharyngeal physical therapy: Didgeridoo

- 25 patients
  - Moderate OSA (AHI 15-30)
  - 14 didgeridoo group
  - 11 control group
- Didgeridoo group
  - 4 lessons
  - Practiced
    - Minimum 20 min/day
    - At least 5 day/week
    - For 4 months
- Results

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<tr>
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<th>Didgeridoo</th>
<th>Control</th>
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<tr>
<td>AHI</td>
<td>22.3 → 11.6</td>
<td>19.9 → 15.4</td>
</tr>
<tr>
<td>ESS</td>
<td>11.8 → 7.4</td>
<td>11.0 → 9.6</td>
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### Oropharyngeal physical therapy: SLP exercises

- 31 patients
- Moderate OSA (AHI 15-30)
- Randomized to
  - Oropharyngeal exercises (n=16)
  - Sham control (n=15)
- PSG and subjective questionnaires at baseline and at 3 months
- Single SLP
- Weekly supervised session for 30min
- Home exercises for 30min daily
- Compliance assessed with diary/self-reporting

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<tr>
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<th>Control</th>
<th>Therapy</th>
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<tbody>
<tr>
<td>AHI</td>
<td>23.9 → 24.3</td>
<td>21.3 → 12.8</td>
</tr>
<tr>
<td>ESS</td>
<td>14 → 12</td>
<td>14 → 8</td>
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• Medical therapy is the core of OSA management
• Otolaryngologists are uniquely positioned to take ownership and provide comprehensive high-quality medical therapy.
• CPAP and oral appliance therapy
  – Standard first-line options
  – Evaluate both subjective and objective results and adherence (data card download technology)
• Suboptimal adherence rates with CPAP and oral appliance therapy necessitate additional treatment options
• Phenotype patients based on anatomy and pathophysiology (rather than AHI alone)
  – Customize treatment accordingly
  – Strongly consider combination therapy