Diagnosing Pediatric OSA Without a Sleep Study: Can it Be Done?

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Disclosures

• Respiratory Intelligence Inc.
  • Shareholder, Board Member
• 2 Patents in review
Overview

• Current practice patterns
• The changing definition of a sleep study
• Accuracy of history and physical exam
• New methods for diagnosing OSA
• New technologies for home sleep testing in children and adults

Current Practice patterns

• 3-10% of children receive a sleep study
• **AASM Position Statement on HSAT in Pediatrics (2007)**
  
  Use of a home sleep apnea test is not recommended for the diagnosis of obstructive sleep apnea in children. The ultimate judgment regarding propriety of any specific care must be made by the clinician, in light of the individual circumstances presented by the patient, available diagnostic tools, accessible treatment options, and resources.
Access to Preoperative Sleep Studies

• Majority of children are diagnosed with OSA based on clinical history and exam
• Survey of 603 Otolaryngologists
  • 3-10% of children receive sleep study before undergoing surgery

“It is important for children exhibiting signs & symptoms of OSA to get a comprehensive diagnosis by having an overnight, in-laboratory sleep study.”

Polysomnography

• Sleep stage
• Muscle tone
• Thoracoabdominal movements
• Airflow
• Oxygen saturation
• Chin movement
• Body position
• Cardiac rhythm
Confounding Factors
- Allergic Rhinitis
- Recurring URIs
- Weight gain after surgery
- Other sleep disorders

Goals of Preop Evaluation
- Differentiate snoring vs. OSA
- Identify site(s) of obstruction
- Decide if a sleep study is necessary
- Determine candidacy for surgery versus conservative management
- Identify possible non-responders and counsel parents on postop management

Screening with Questionnaires
- Epworth Sleepiness Scale – widely used
- No-Apnea – neck circumference and age
- STOP-Bang – 8 yes or no questions
- OSA-18 – QOL survey 5 sections (pediatrics)
- NoSAS – neck circumference, BMI, snoring, age > 55 years, gender
Accuracy of Screening Tools

- Cross sectional study
- STOP-Bang and NoSAS were superior
- Poor prediction with ESS

### Predictive parameters of all models (n = 2591)

<table>
<thead>
<tr>
<th>AHI &gt; 5.0/h</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>No-Apneas</td>
<td>84.5 (83.0–85.3)</td>
<td>88.2 (87.2–89.1)</td>
<td>74.7 (73.7–75.7)</td>
<td>43.4 (44.6–45.2)</td>
<td>68.7 (67.9–69.6)</td>
</tr>
<tr>
<td>STOP-Bang</td>
<td>58.2 (55.0–61.3)</td>
<td>91.1 (90.1–92.1)</td>
<td>90.9 (89.6–92.1)</td>
<td>55.9 (53.5–58.3)</td>
<td>71.2 (69.9–72.6)</td>
</tr>
<tr>
<td>NoSAS</td>
<td>55.5 (53.0–58.9)</td>
<td>65.8 (63.9–67.7)</td>
<td>45.0 (43.8–46.2)</td>
<td>77.3 (75.5–79.0)</td>
<td>59.3 (57.2–61.4)</td>
</tr>
</tbody>
</table>

Duarte RL, Magalhães F. Predicting Obstructive Sleep Apnea in Patients with Insomnia: A Comparative Study with Four Screening Instruments. Lung. 197(4), 2019

Finding Alternatives to Polysomnography
Early Attempts

• Lieberman et al. (1986)
  • Acoustic analysis of snoring and stridor in children
• Carin et al. (1999)
  • Evaluation of home audio recordings


• 1986
  • Acoustic analysis of 65 patients, 5 children
  • Power spectral density analysis
  • Laryngomalacia, Croup, Subglottic Foreign Body, 2 cases severe OSA
  • Reliable pattern detection
Evaluation of Home Audiotapes as an Abbreviated Test for Obstructive Sleep Apnea Syndrome (OSAS) in Children

Carin Lamm, MD,1* John Mandelli, PhD,2 and Meyer Kattan, MD1

- 1999
- 29 children
  - 15 primary snoring
  - 14 OSA
- 15 minute audio recording
- 7 observers listened to audio
- Median sensitivity 71%
- Median specificity 80%

TABLE I—Physical Characteristics and Positive Questionnaire Responses for Patients With Primary Snoring and OSAS

<table>
<thead>
<tr>
<th>Nocturnal symptoms</th>
<th>Primary snoring (AHI &lt;5)</th>
<th>OSAS (AHI &gt;5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>15</td>
<td>14</td>
</tr>
<tr>
<td>Age (years)2</td>
<td>6.0 ± 4.1</td>
<td>5.5 ± 4.5</td>
</tr>
<tr>
<td>Enlarged tonsils (grades 3, 4)3</td>
<td>42.9%</td>
<td>66.2%</td>
</tr>
<tr>
<td>BMI &lt;15th percentile</td>
<td>21.6%</td>
<td>16.7%</td>
</tr>
<tr>
<td>BMI ≥85th percentile</td>
<td>28.6%</td>
<td>58.3%</td>
</tr>
<tr>
<td>Obstructed apnea</td>
<td>64.7%</td>
<td>66.7%</td>
</tr>
<tr>
<td>Loud snoring</td>
<td>85.7%</td>
<td>60.9%</td>
</tr>
<tr>
<td>Struggles to breathe</td>
<td>78.6%</td>
<td>71.4%</td>
</tr>
<tr>
<td>Restless sleep</td>
<td>35.7%</td>
<td>46.2%</td>
</tr>
<tr>
<td>Diaphoresis</td>
<td>30.8%</td>
<td>27.6%</td>
</tr>
<tr>
<td>Snoring, respiratory pauses</td>
<td>69.2%</td>
<td>90.9%</td>
</tr>
<tr>
<td>Daytime mouth breather</td>
<td>38.5%</td>
<td>60.0%</td>
</tr>
</tbody>
</table>

1AHI, apnea hypopnea index; BMI, body mass index (kg/m2). Questions were scored as 1, never; 2, rarely; 3, sometimes; 4, most nights; and 5, every night. Positive responses were those scored 4 or 5. There were no statistically significant differences between the two groups using the chi square test, or when sample size was too small, Fisher’s exact test for 2 × 2 tables.
2Values are means ± standard deviation.
3Tonsil size was graded 0–4; 0, not visible; 4, touching in the middle.11

Sleep Staging

- Electroencephalography (EEG)
- Electromyography (EMG)
- Electrooculography (EOG)

Identify sleep-wake state
Sleep Staging

- Electroencephalography (EEG)
- Electromyography (EMG)
- Electrooculography (EOG)

Challenges to Polysomnography

- Resource intensive, expensive and uncomfortable
- Certified Sleep Center, physician provides report
- No technological changes for past 20 years
- Limited access
Goals for Ideal Home Pediatric PSG

- Reduction of sensor count
- Cordless acquisition of signals (strangulation risk)
- Apply new metrics
- Reduce number of channels necessary
- Validated auto-scoring system that fulfills requirements of AASM

### SCOPER Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Modality</th>
<th>Reference Study</th>
<th>Ease of use</th>
<th>Predictive Accuracy</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep</td>
<td>Electroencephalography</td>
<td>Chen et al. [22]</td>
<td>Difficult</td>
<td>Moderate</td>
<td>High</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Electrocardiography</td>
<td>Stulz et al. [13]</td>
<td>Difficult</td>
<td>Moderate</td>
<td>High</td>
</tr>
<tr>
<td>Electrocardiography</td>
<td>Heart rate variability</td>
<td>Nishikawa et al. [25]</td>
<td>Moderate</td>
<td>Moderate</td>
<td>High</td>
</tr>
<tr>
<td>Perinatal arterial tonometry</td>
<td>Tapia et al. [34]</td>
<td>Su et al. [50]</td>
<td>Difficult</td>
<td>Moderate</td>
<td>High</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>Oximetry</td>
<td>Gao et al. [54]</td>
<td>Difficult</td>
<td>Modest</td>
<td>Moderate</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>Cardiographic</td>
<td>Ulmer et al. [54]</td>
<td>Moderate</td>
<td>Moderate</td>
<td>High</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>Electrocardiography</td>
<td>Melzer et al. [84]</td>
<td>Moderate</td>
<td>Moderate</td>
<td>High</td>
</tr>
<tr>
<td>Position</td>
<td>Ballistax sensor</td>
<td>da Prato et al. [24]</td>
<td>Moderate</td>
<td>Moderate</td>
<td>High</td>
</tr>
<tr>
<td>Position</td>
<td>Respiratory Inductance</td>
<td>Mason et al. [82]</td>
<td>Moderate</td>
<td>Moderate</td>
<td>High</td>
</tr>
<tr>
<td>Effort</td>
<td>Plethysmography</td>
<td>Griffiths et al. [87]</td>
<td>Difficult</td>
<td>Moderate</td>
<td>High</td>
</tr>
<tr>
<td>Effort</td>
<td>Nasal flow sensors</td>
<td>Sorensen et al. [94]</td>
<td>Difficult</td>
<td>Moderate</td>
<td>High</td>
</tr>
<tr>
<td>Effort</td>
<td>Sleep apnea monitors</td>
<td>Law et al. [25]</td>
<td>Difficult</td>
<td>Moderate</td>
<td>High</td>
</tr>
</tbody>
</table>

Bertoni D, Isaiah A. Towards Patient-centered Diagnosis of Pediatric OSA – A Review of Biomedical Engineering Strategies. Review of Medical Devices. 16(9), 2019
New Parameters and Technologies

- Heart rate variability (HRV)
- Peripheral arterial tonometry (PAT) and Pulse Transit Time (PTT)
- Watch-PAT®
- Oximetry
- ApneaLink™
- Actigraphy
- Smartphone apps (MotionX 24/7®)
- Machine learning and predictive algorithms

Actigraphy

- Accelerometer
- Oura ring
- Motionlogger® Sleep Watch
- Actiwatch-2® (Philips)
- Fitbit Ultra®
- UP®
Reliability of Actigraphy

• Meltzer et al.
  • Actiwatch-2: Acceptable sensitivity (88%), but weak specificity (46%)
  • Motionlogger Sleep Watch: underestimated total sleep time significantly
• Sleep-related interruption rather than obstructive events

OURA Ring

• Optical sensors and accelerometer
• Proprietary algorithm
• Independent study found accurate detection of sleep-wake cycles and sleep stage

Zambotti M, Rossa L, Colrain I. The Sleep of the Ring: Comparison of the OURA Sleep Tracker Against Polysomnography. Behavioral Sleep Medicine. 17(2), 2019
Watch-PAT® Pediatric Studies

- 38 adolescents
- Correlation, agreement and concordance in AHI SpO₂ nadir
- High correlations in all parameters and OSA severity

Watch-PAT® Adult Studies

- 2019
- 39 adults
- Split night PSG (with and without CPAP)
- PSG and Watch-PAT correlation

<table>
<thead>
<tr>
<th>Table 1</th>
<th>AHI, REM AHI and Non-REM AHI scores revealed with PSG and Watch PAT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AHI</td>
</tr>
<tr>
<td>PSG</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Median (min-max)</td>
<td>28.3 (15.9-95.2)</td>
</tr>
<tr>
<td>Watch PAT</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Median (min-max)</td>
<td>26.9 (3.5-97.2)</td>
</tr>
<tr>
<td>p value (Wilcoxon Signed Rank Test)</td>
<td>0.428</td>
</tr>
</tbody>
</table>


SOMNOtouch™

- Can combine with home sleep camera

- 10 Channel Headbox with 6 EEG/EOG, Ground, Reference, Continuous Impedance, 1 EMG
- Combined sensor for effort, 1 channel ECG, 2 EMG for PLM
- Pressure (Flow & Snore)
- Effort (Thorax / Abdomen)
- SpO2, Pulse rate
- Body position
- Movement (Sleep / Wake Determination)
- CPAP/BiPAP – Pressure
- Up to 16 channels can be connected via the two open auxiliary connectors, e.g. PLM, ECG, EEG, EOG, EMG.

ApneaLink™ Plus

- Type III home testing device
- Respiratory effort, pulse, oxygen, nasal flow
- Reports apneas, hypopneas, flow limitation, snoring, “probability” of Cheyne-Stokes respiration
- Scoring: manual, Auto AASM, Auto scoring
- Cho et al.
- 149 patients
- Manual scoring was most accurate, auto scoring inflated AHI

Cho J, Kim HJ. Validation of ApneaLink Plus for the diagnosis of sleep apnea. Sleep Breath. 21(2), 2017
Pulse Transit Time (PTT)

- Time it takes a pulse wave to travel between arterial sites
- Affected by arterial tone and left ventricular pre-ejection period
  - Increase in arterial tone = decrease in transit time
- Can also detect central apnea
- Role as a screening tool, cannot replicate PSG

The Future of Sleep Testing

- Prove “non-inferiority” rather than mirroring the PSG
- Adult in-home testing offers a precedent for children
- Combination of sensors (Actigraphy and PAT)
- A huge unmet need for HSAT in Children (and Adults)
- More understanding of morbidity in children is needed
Snoring Often Persists After Surgery

- Up to 30% patients have persistent OSA after surgery
  - Higher in Obesity, Down Syndrome, Craniofacial Abnormalities
- 3 month trial Montelukast (Singulair) and Nasal Steroids
- Postop Sleep Study if symptoms persists
- Contributing Factors: recent weight gain, seasonal allergies, septal deviation

Summary

- History and physical exam alone poorly predict OSA, some questionnaires are more sensitive than others
- AASM, AAP and academic societies still support PSG as the gold standard
- HSAT is accepted in adults, not sufficiently validated in children
- Technology will likely be available and validated in the next 5 years
- Proving non-inferiority to PSG
- There continues to be a huge unmet need for reliable HSAT in children
Thank You