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Disclosures

• No relevant financial disclosures

Diagnostic Testing Shift: Drivers of Change

• Economic challenges due to rapid increases in:
  • Demand for sleep medicine services
  • # of sleep centers
  • Diagnostic testing
  • PAP prescriptions

• Accessibility challenges
  • 12-18 million US adults with undiagnosed OSA

• Technologic changes
  • Greater array of less expensive, yet underutilized testing options

Payers:

Savings
opportunity

Shift to patient-management outcomes
  • Equivalent/improved outcomes data with home testing
Growth in AASM Accredited Centers

Increase in PSG Volumes for Medicare

Testing expenditures ↑ 279%

PAP Equipment Volume Growth

• CPAP equipment
  • Annual growth: 16% over past 6 yrs
  • CPAP Sales 2013: $1 billion
  • Mask sales 2013: $675 million

Larry Epstein AASM Course 2013
Economic Impact of Greater Use of Home Testing

Institute for Clinical & Economic Review, Diagnosis and Treatment of Obstructive Sleep Apnea in Adults, Jan 2013

$35 million potential savings

Mulgrew Study

- 68 patients with new, at least moderate OSA
- Randomized:
  - In-lab titration
  - Auto-PAP with conversion to fixed PAP
- Assess outcomes at 3 months

Ann Intern Med 2007; 146:157
At 3 Months…

- No differences in:
  - AHI during final PSG
  - ESS
  - SAQLI scores

- CPAP hrs/night better in HST group

- Conclusion: PSG confers no advantage over PM/auto-CPAP titration in initial management of high probability OSA

Mulgrew AT. Ann Intern Med 2007; 146:157

Lab versus Home OSA Testing

- For uncomplicated, moderate-severe OSA, no differences:
  - CPAP adherence
  - Sleepiness improvements
  - Quality of life improvements

Antic N. AJRCCM 2009.
Skomro RP. Chest 2010.
Kuna S. AJRCCM 2011.
Rosen CL. Sleep 2012

A Multicenter Randomized Trial of Portable Sleep Studies and Positive Airway Pressure Autotitrator Versus Laboratory-Based Polysomnography for the Diagnosis and Treatment of Obstructive Sleep Apnea: The HomePAP Study

- 7 Centers; non-inferiority study

- High pretest prob of mod-severe OSA:
  * ESS ≥ 12
  * Adjusted neck circumference ≥ 43 cm:
    * Neck + snoring (3) + HTN (4) + apneas (4)

- AHI/RDI ≥ 15

Sleep 2012; 35:757
**HomePAP Arms**

Lab (n=92)
- AHI ≥ 15 (mean 48)
- AHI < 10 on CPAP

Home (n=105)
- Embletta
- REI ≥ 15 (mean 40)
- AHI < 10 on APAP

**HomePAP Primary Endpoints**

<table>
<thead>
<tr>
<th></th>
<th>Lab</th>
<th>Home</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPAP acceptance</td>
<td>94%</td>
<td>93%</td>
<td>NS</td>
</tr>
<tr>
<td>Time to treatment</td>
<td>38 ± 29</td>
<td>33 ± 27</td>
<td>NS</td>
</tr>
<tr>
<td>(days)</td>
<td></td>
<td></td>
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<tr>
<td>1-month adherence</td>
<td>224 ± 121</td>
<td>244 ± 141</td>
<td>NS</td>
</tr>
<tr>
<td>(mins)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-month adherence</td>
<td>219 ± 155</td>
<td>281 ± 126</td>
<td>0.01</td>
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<tr>
<td>(mins)</td>
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</table>

*Sleep 2012; 35:757*

**HomePAP Secondary Outcomes**

- ESS
- FOSQ
- SAQLI
- SF-36
- Home arm failure rate:
  - Diagnostic: 12%
  - Auto-titration: 10%
- Successful PAP titration: 85% both groups

*Sleep 2012; 35:757*
Caveats about Home Testing Studies

- Pre-testing Sleep evaluation in all subjects
- Only mod-severe OSA subjects included
- No sleep/cardioresp co-morbidities
- Drop outs 11-43%

Initial Response to Home Testing by Many Sleep Specialists

“The Home Sleep Study State”
Home testing for OSA Suspects unless:

- Chronic pulmonary disease
- Neuromuscular/neurodegenerative disorder
- Significant cardiac disease
- BMI ≥ 50
- Obesity hypoventilation syndrome
- One or more of following sleep disorders
  - PLMD
  - Parasomnia
  - Narcolepsy
  - Central sleep apnea
- Child/adolescent
- Prior home test indeterminate/technically inadequate
- Unfit circumstances for home testing

Lab-based PSG in previously diagnosed OSA if:

- Before surgery for OSA
- Assess response to:
  - Oral appliance
  - Upper airway surgery
  - Bariatric surgery
- Split-night PAP titration not feasible or unsuccessful:
- Follow-up titration if new or persistent symptoms despite CPAP

Abrupt Change in Site of Testing

Courtesy Lawrence Epstein, MD: Data from Sleep HealthCenters for one insurance company before and after implementation of sleep benefit management program requiring approval/preauthorization of studies and use of HST unless meet criteria set to.
### Finances

<table>
<thead>
<tr>
<th>Test Type</th>
<th>CMS Reimbursement</th>
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</thead>
<tbody>
<tr>
<td>Full-night lab diagnostic PSG</td>
<td>$645.76</td>
</tr>
<tr>
<td>Split-night lab PSG</td>
<td>$677.40</td>
</tr>
<tr>
<td>Out of center test</td>
<td>$183.38</td>
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</table>

#### Suspected OSA?

- **No**
- **Yes**: Eval for other sleep disorder; consider in-lab PSG

#### Co-morbid medical/sleep disorders?

- **Yes**: In-lab PSG
- **No**: Home Study

- **Severe CHF**
- **Brittle dysrhythmias**
- **Severe COPD**
- **Neuromuscular disease**
- **O₂ dependence**
- **Cognitive impairment**
OSA diagnosed?  
- No → In lab-PSG  
- Yes → Treatment

Mayo Utilization of Home Testing

<table>
<thead>
<tr>
<th>Classification of OSA Testing</th>
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<tbody>
<tr>
<td>Study Type</td>
</tr>
<tr>
<td>------------</td>
</tr>
<tr>
<td>Type 1</td>
</tr>
<tr>
<td>Type 2</td>
</tr>
<tr>
<td>Type 3</td>
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<tr>
<td>Type 4</td>
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</table>

Modified from: Ferber R. Sleep 1994; 17:378
Proposed New Classification:
SCOPER

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Options</th>
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<tbody>
<tr>
<td>Sleep</td>
<td>Sleep time; Actigraphy</td>
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<tr>
<td>CV</td>
<td>ECG; Peripheral Tonometry</td>
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<tr>
<td>Oximetry</td>
<td>Desaturations (finger; forehead)</td>
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<tr>
<td>Position</td>
<td>Visual vs non-visual</td>
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<tr>
<td>Effort</td>
<td>RIP; Peizo</td>
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<tr>
<td>Respiratory</td>
<td>Nasal pressure; Oronasal Thermal</td>
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</tbody>
</table>

Collop NA. J Clin Sleep Med 2011; 7:531

Embletta

- Airflow
  - Nasal pressure
  - Oronasal thermal sensor
- Snoring
- Respiratory effort
  - Chest and abdominal RIP
- SpO2
- Pulse
- Body position

Type 3 or S0 C4 O1 P2 E1 R1

Assessment of Home Device:
Issues to Consider

- Self-management vs outsourcing
- # of sensors
- Cost per study (cost of device; supplies)
- Scoring (local vs company)
- Software integration
- Ease of use/failure rate
- Chain of custody
Additional Terminology

- PSG: Apnea-hypopnea index (AHI):
  Apneas + hypopneas/hour sleep

- Home test: Respiratory event index (REI):*
  Apneas + hypopneas/recording hour

*Collop NA. J Clin Sleep Med 2011; 7:531

REI usually < AHI

Potential Advantages of Home Testing

- More comfortable, less intimidating than lab-based PSG
- More accessible for less mobile patients or who might find PSG challenging
- Flexible setting: home, hospital room, hotel
- Device less costly to purchase than PSG equipment
- Virtual sleep center – number of patients that can be studied is not limited by the size of sleep center

Potential Disadvantages of Home Testing

- Diagnostic focus limited to disordered breathing
  - RERAs, hypoventilation challenging to detect
- Limited technician ability to address patient problems
- Traditional PAP titration not possible
- Low margin procedure
- Equipment problems and artifacts cannot be corrected

3% to 20% data loss in unattended home studies
Effect of Recording Duration on the Diagnostic Accuracy of Home Sleep Testing for Obstructive Sleep Apnea

Wittine LM, Olson EJ, and Morgenthaler TI

Study Purpose

- To determine the minimum recording time to project an accurate diagnosis of OSA for unattended home sleep testing.

Hypothesis

- 120 -180 minutes of valid recording time on HSTs will be sufficient to accurately diagnosis presence and severity of OSA.

“AHI derived from the first 2 or 3 hours of sleep is of sufficient diagnostic accuracy to rule-in OSA at an AHI threshold of 5 in patients suspected of having OSA.”
Methods

• 140 consecutive Emblettta studies
• October 2009 to May 2012

Inclusion Criteria

• Original technician-scored data available

Exclusion Criteria

• Less than 3 hours of recorded data

Original HST Measurements

• Emblettta records from 2200 – 0600
• Technician sets analysis start and stop times
• Establishes the Total Recording Time (TRT)
Original HST Measurements

- Technician manually scores respiratory events
- Establishes the Respiratory Event Index (REITRT)

\[ \text{REITRT} = \frac{\text{Respiratory Events}}{\text{TRT}} \]

Study Design

Data Analysis

- Comparison of REITRT to \( \text{REI(TIME INTERVAL)} \)
  - Paired t-test to evaluate difference
  - Concordance correlation coefficient to evaluate both agreement and correlation
**Mean Difference, Concordance Correlation Coefficients, T-Tests**

Median TRT 475 (446-479), > 360 in 98%, > 420 in 85%

![Graph showing mean difference, concordance correlation coefficients, and T-tests.](image)

**“Best 120 Minutes”**

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<th>Number of Studies</th>
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**REITR vs REIBEST:**

- Mean Difference: 2.16 (0.6-3.7)*
- Concordance Correlation Coefficient: 0.885

**Misclassification of OSA by Severity**

![Graph showing misclassification of OSA by severity.](image)
Data Loss

- 33 (26%) studies with lost, incomplete data
  - Oximeter loss: 13
  - Nasal pressure loss: 13
  - Oximetry loss: 5
  - Battery failure: 2

Conclusions

- 300 minutes of valid recording time during HSTs provides diagnostic evidence of OSA that is not significantly different than longer recording periods

- Shorter recording intervals tend to underestimate the severity of OSA

Reflections on Home Sleep Testing

- Home testing not going away
- Acceptable option in “straight-forward” OSA
- CMS is not mandating home testing
- Recalibration of financial expectations
Reflections on Home Testing

- Patient mix in lab to evolve
  - More complex PAP, O₂ titrations
  - More pediatric patients

- Broader clinical Sleep focus beyond disordered breathing

- Integrated care programs with greater attention to patient outcomes

- Facility reutilization likely; telemedicine and remote monitoring

Reflections on Home Testing

- Greater involvement in DME

- Greater tech involvement in aspects of Sleep care delivered during the day

- Greater focus on cost reduction

- Demand for Sleep care continues to expand which will increase all forms of sleep clinical activities!

Thank you

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