Technologies for the Diagnosis and Monitoring of Sleep Disordered Breathing

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Presentation Overview

• Review current clinical use of polysomnography (PSG) and home sleep apnea testing (HSAT) for the diagnosis of sleep disordered breathing

• Devices and technologies for diagnosing OSA, CSA and hypoventilation
  – Supporting data and current guidelines
Questions for the Panel

• Can HSAT be used for establishing a baseline diagnosis and for the collection of clinical performance data for device trials for OSA, CSA or Primary Snoring?
  – If so, what are the recommended parameters which should be collected by an HSAT (e.g., nasal pressure, oximetry, chest and abdominal respiratory inductance plethysmography)?

• What constitutes a technically adequate test (either PSG or HSAT, if appropriate) for establishing a baseline diagnosis of SDB for device studies (e.g., number of hours, number of nights).
Why Do We Need Objective Testing to Diagnose Sleep Disordered Breathing?

• History alone is not diagnostic
  – Bed partner history of snoring and witnessed apneas:
    • Correct 64% of the time
  – Expert healthcare provider subjective impression:
    • Correctly identifies only 50% of sleep apnea patients

• Clinical tools, questionnaires and prediction algorithms alone have a low level of accuracy for the diagnosis of OSA in the clinic-based setting

## Classification of “Sleep” Studies

<table>
<thead>
<tr>
<th>Sleep Test</th>
<th>Description</th>
<th>Personnel</th>
<th>Minimum Signals Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1</td>
<td>Standard PSG performed in a sleep lab</td>
<td>Attended</td>
<td>≥ 7 signals including: EEG, EOG, chin EMG, ECG, airflow, respiratory effort and oxygen saturation</td>
</tr>
<tr>
<td>Type 2</td>
<td>Comprehensive portable PSG</td>
<td>Unattended</td>
<td>Same as type 1</td>
</tr>
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<td>Portable testing limited to sleep apnea</td>
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<td>≥ 4 signals including: ECG or heart rate, oxygen saturation, and at least 2 channels of respiratory movement or resp movement and airflow</td>
</tr>
<tr>
<td>Type 4</td>
<td>Continuous recording of 1 or 2 signals or any test not fitting into the other categories</td>
<td>Unattended</td>
<td>≥ 1</td>
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</tbody>
</table>
### SCOPER Categorization System

<table>
<thead>
<tr>
<th>Sleep</th>
<th>Cardiovascular</th>
<th>Oximetry</th>
<th>Position</th>
<th>Effort</th>
<th>Respiratory</th>
</tr>
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<tbody>
<tr>
<td>S₁ – Sleep by 3 EEG channels with EOG and chin EMG</td>
<td>C₁ – more than 1 ECG lead – can derive events</td>
<td>O₁ – Oximetry (finger or ear) with recommended sampling</td>
<td>P₁ – Video or visual position measurement</td>
<td>E₁ – 2 RIP belts</td>
<td>R₁ – Nasal pressure and thermal device</td>
</tr>
<tr>
<td>S₂ – Sleep by less than 3 EEG with or without EOG or chin EMG</td>
<td>C₂ – Peripheral arterial tonometry</td>
<td>Oₓ – Oximetry (finger or ear) without recommended sampling (per Scoring Manual) or not described</td>
<td>P₂ – Non-visual position measurement</td>
<td>E₂ – 1 RIP belt</td>
<td>R₂ – Nasal pressure</td>
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<td>S₃ – Sleep surrogate: e.g. actigraphy</td>
<td>C₃ – Standard ECG measure (1 lead)</td>
<td>O₂ – Oximetry with alternative site (e.g. forehead)</td>
<td>E₃ – Derived effort (e.g. forehead versus pressure, FVP)</td>
<td>R₃ – Thermal device</td>
<td></td>
</tr>
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<td>S₄ – Other sleep measure</td>
<td>C₄ – Derived pulse (typically from oximetry)</td>
<td>O₃ – Other oximetry</td>
<td>E₄ – Other effort measure (including piezo belts)</td>
<td>R₄ – End-Tidal CO₂ (ETCO₂)</td>
<td></td>
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<tr>
<td></td>
<td>C₅ – Other cardiac measure</td>
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<td></td>
<td>R₅ – Other respiratory measure</td>
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Proper oximetry sampling is defined as 3 s averaging and a minimum of 10 Hz sampling rate (25 Hz desirable). ¹⁻³ EEG channels defined as frontal, central and occipital. EEG, electroencephalography; EOG, electrooculography; EMG, electromyography; ECG, electrocardiography; RIP, respiratory inductance plethysmography.

Collop N. J Clin Sleep Med 2011;7(5):531-548
# Updated: AASM Classification of “Sleep” Studies

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Attended Polysomnography (PSG)

• The “gold standard”
• Monitors:
  – Brainwaves
  – Eye movements
  – Breathing
  – Leg movements
  – EKG
• OSA diagnosis:
  – ≥ 5 events/hour
Type 2 Studies: Sleep Heart Health Study

• Prospective cohort study n= 6441
• Initiated in 1998
• Portable testing:
  – Unattended in-home full polysomnography
• Limitations for general population
  – Highly standardized
  – Significant tech and patient teaching
  – Standardized scoring at one central site
  – Difficult to replicate in usual practice
  – Not cost effective

PSG: Obstructive Sleep Apnea (OSA)

Recurrent Obstructive Apneas with Associated Oxygen Desaturations
PSG as the Gold Standard for OSA Diagnosis

- Polysomnography is the standard diagnostic test for the diagnosis of OSA in adults in whom there is a concern for OSA based on a comprehensive sleep evaluation
  - Widely accepted as the gold standard
  - Used as comparison for other diagnostic tests
  - Can identify other sleep disorders concurrently
  - Can be used for the diagnosis and treatment of SDB

Split-Night PSG

- A split-night diagnostic protocol, rather than a full-night diagnostic protocol, be used if clinically appropriate
  - Moderate to severe OSA is observed during a minimum of 2 hours of recording time on the diagnostic PSG
  - At least 3 hours are available for PAP titration
- Recommendation based on 9 studies
  - Excellent consistency of the AHI (3 hours vs full night)
  - Similar improvement in AHI and PAP adherence
  - Limited data, mostly retrospective

Attended PSG as the Gold Standard: Questions to Address

• What is an adequate or successful test?
  – Recording time vs sleep time
  – Sleep stages
  – Does it differ for high and low clinical suspicion patients
• How often do we encounter a PSG failure?
• How often does PSG miss a diagnosis of OSA or misclassify its severity?
• What is the night-to-night variability of the AHI?
• How often do we achieve an optimal CPAP titration?
What is an adequate or successful PSG?

How often do we encounter a PSG failure?
Is This a Successful PSG?
How Often is this Observed?
Or This?
How often does PSG miss a diagnosis of OSA or misclassify its severity?
Hypopneas: Where We Stand Today

• **Recommended 1A**: Score a respiratory event as a hypopnea if ALL of the following criteria are met:
  – The peak signal excursions drop by greater than or equal to 30% of pre-event baseline using nasal pressure (diagnostic study), PAP device flow (titration study), or an alternative hypopnea sensor (diagnostic study).
  – The duration of the greater than or equal to 30% drop in signal excursion is greater than or equal to 10 seconds.
  – There is a $\geq 3\%$ oxygen desaturation from pre-event baseline and/or the event is associated with an arousal.

• **Acceptable 1B**: Score a respiratory event as a hypopnea if ALL of the following criteria are met:
  – The peak signal excursions drop by greater than or equal to 30% of pre-event baseline using nasal pressure (diagnostic study), PAP device flow (titration study), or an alternative hypopnea sensor (diagnostic study).
  – The duration of the greater than or equal to 30% drop in signal excursion is greater than or equal to 10 seconds.
  – There is a $\geq 4\%$ oxygen desaturation from pre-event baseline.
Changing Hypopnea Definition Changes OSA Definitions

AASM recommended criteria: Score a hypopnea if all of the following are present:
- Nasal pressure signal excursions (or those for the alternative hypopnea sensor) drop ≥ 30% of baseline for at least 10 sec
- There is a ≥ 4% desaturation from pre-event baseline
- At least 90% of the event’s duration must meet the amplitude reduction of criteria for hypopnea

AASM alternative criteria: Score a hypopnea if all of the following are present:
- Nasal pressure signal excursions (or those for the alternative hypopnea sensor) drop ≥ 50% of baseline for at least 10 sec
- There is a ≥ 3% desaturation from pre-event baseline or the event is associated with an arousal
- At least 90% of the event’s duration must meet the amplitude reduction of criteria for hypopnea

AASM clinical research criteria (Chicago Criteria): Score a hypopnea if any of the following are present:
- Nasal pressure signal excursions (or those for the alternative hypopnea sensor) drop ≥ 50% of baseline for at least 10 sec
- The amplitude of the airflow or chest wall movement decreases to a level above 50% of the amplitude of “baseline” and is associated with a > 3% transient oxygen desaturation and/or an arousal.

Kuna S et al. SLEEP 2013;36(4):583-589
Is There Night to Night Variability in the AHI?

• Yes!
• Several studies demonstrate significant inter-individual night-to-night variability in the AHI
  – First night effect
  – Body position
• Tends to be greatest in patients with less severe disease

Ahmadi N et al Sleep and Breathing 2009;13:221-226
Many Patients May Not Achieve an Optimal CPAP Titration

- Quality of Titration:
- Optimal:
  - AHI < 5 with supine REM
- Good:
  - AHI < 10 with supine REM
- Adequate:
  - AHI < 75% of baseline or
  - No supine REM
- Inadequate: Other

PSG Conclusions

- Attended PSG is the standard test for diagnosing OSA

- Advantages:
  - Used as comparison for other diagnostic tests
  - Can identify other sleep disorders concurrently
  - Split-night PSG can be used in the appropriate setting to diagnosis and determine treatment

- Disadvantages:
  - Expensive
  - Not always successful
  - One night might not be enough
Home Sleep Apnea Testing (HSAT)

- Best for diagnosis in high suspicion patients
- Does not rule out disease
- Best device is not known
- Not as simple as it looks
Terminology for Home Sleep Apnea Testing
2007 Recommendations from the AASM on HSAT for OSA

• As part of a comprehensive clinical evaluation by a trained sleep specialist

• High pretest probability of moderate to severe OSA
  – Without comorbid medical conditions or suspected comorbid sleep disorders

• Records a minimum of airflow, respiratory effort and pulse oximetry
  – More recently recognized other types of devices

• Not recommended for general screening of asymptomatic patients

• PSG, or HSAT with a technically adequate device, can be used for the diagnosis of OSA in uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA

• PSG, rather than HSAT, should be used for the diagnosis of OSA in patients with significant hypoventilation, chronic opioid medications, a history of stroke or severe insomnia
Type 3 HSAT Devices

• Portable sleep testing limited to sleep apnea

• Channels monitored:
  – ≥ 4 signals including:
    • ECG or heart rate
    • oxygen saturation, and
    • At least 2 channels of respiratory movement or respiratory movement and airflow

• Really “portable sleep apnea testing” as sleep is not measured
Type 3 HSAT Devices

1. Respiratory Effort Sensor Belt
   Measures respiratory effort

2. Nasal Cannula
   Measures airflow

3. Pulse oximeter
   Measures oxygen saturation levels

4. Measures heart rate
Type 3 HSAT: Severe OSA
Type 3 Device Output
HSAT Supporting Data

- WatchPAT is adequate for diagnosing OSA
  - 3 IA and 4 IIA studies
- Devices that measure nasal pressure plus effort are adequate to diagnose OSA
  - 2 IA, 1 Ib, and 1 IVa
  - Embletta and Stardust II
- Devices that measure nasal pressure without effort are adequate to diagnose OSA
  - Apnea link (1 IA) and ARES (2 IA and 1 IIA studies)
- Thermal sensing device alone without effort measurement is inadequate for diagnosing OSA

## RCTs Outcomes Data Supporting HSAT for OSA

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<td>*Lower cost in HST group</td>
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How Much HSAT Data Are Required?

• A single night of HSAT should be sufficient with a technically adequate test in the proper patient population
  – Limited data to support the superiority of multiple nights vs one night of testing
  – Multiple nights may increase costs

• Four hours of recording time with adequate flow and oximetry data during the habitual sleep period
  – Very limited body of evidence

Autoscoring: How Good Is It?
Autoscororing: How Good Is It?

• Agreement between automated and manual scoring of home sleep recordings varies based on the device and algorithm used:
  – Type 3 HSATs: AHI correlation: 0.64 to 0.98
  – Range of AHI difference: 5 to 8 events/hr

• Conclusion: Raw data must be reviewed
  – Due to limitations of current automatic scoring algorithms that restrict their diagnostic accuracy

Aurora R et al. CHEST 2015;147:719-727
Punjabi N et al. Sleep 2015;38:1555-1566
Type 3 HSATs: The Good and the Bad

• Advantages:
  – Lower cost than PSG
  – Adequate for diagnosing OSA
  – Similar outcomes to PSG in patients with a high clinical suspicion of uncomplicated moderate to severe OSA

• Disadvantages (potential):
  – Data loss
  – Underestimation of OSA severity
  – False negative tests
  – Limited data in low risk and asymptomatic populations
  – Limited data in patients with comorbid cardio-respiratory disease, neuromuscular weakness or comorbid sleep disorders
  – Limited chain of custody options
Type 4 Devices

- Unattended continuous recording of 1 or 2 signals or any test not fitting into other categories
ARES©: Watermark/Sleepmed
ARES Device: Watermark/Sleepmed

ARES = Apnea Risk Evaluation System
ARES

• Head-mounted device which contains:
  – Limited forehead EEG and EOG
  – Actigraphy
  – Head position
  – Snore microphone
  – Nasal pressure
  – Oximetry
  – Effort band is available
    • Not included with standard kit
    • Addition limits other channels (EEG and EOG)
    • Validation data is based on device without effort band
ARES: OSA

5 Minute Epoch
ARES Results Based on Pre-Test Risk

Figure 1—Bar graph showing ARES portable recording outcomes (AHI and RDI severity) based on pretest risk and severity for OSA using the ARES Screener Questionnaire.

n = 193, 221

HSAT Supporting Data

• WatchPAT is adequate for diagnosing OSA
  – (3 IA and 4 IIA studies)

• Devices that measure nasal pressure plus effort are adequate to diagnose OSA
  – Embletta and Stardust II

• Devices that measure nasal pressure without effort are adequate to diagnose OSA
  – Apnea link (1 IA) and ARES (2 IA and 1 IIA studies)

• Thermal sensing device alone without effort measurement is inadequate for diagnosing OSA

Watch PAT

WatchPAT 100  

WatchPAT 200 U (Unified)
Watch PAT: What Does it Measure?

- Heart rate
- Pulse oximetry
- Actigraphy
- Body Position
- Peripheral Arterial Tonometry (PAT) signal
- Sleep staging via proprietary algorithms
- No airflow measurement
- Optional:
  - Snoring sensor
  - Respiratory effort sensor
Watch PAT

• PAT signal:
  ![PAT signal image]

• Over 100 peer reviewed studies supporting its validity and reliability
  – Only device validated for use in 3rd trimester of pregnancy

• High degree of correlation with PSG
  – AHI/RDI: R = 0.85 to 0.96

• High reliability

• Failure rate of < 1% in clinical studies

• Contraindications:
  – Pacemaker
  – Peripheral neuropathy

Bar A et al. Chest 2003;123:695-703
Pittman D et al. Sleep 2004;27:923-933
Zou D et al. Sleep 2006;29:367-374
Watch PAT

• Advantages:
  – Small, easy to use for patients
  – Low failure rate
  – Autoscorering algorithm makes interpretation quick
  – Easy chain of custody
Watch PAT

• **Potential disadvantages:**
  – No airflow measurement
  – Black box assessment
    • All validation data based on autoscoring algorithm
  – No true interpretation of the raw data
    • Atlas available, but raw signal difficult to interpret
    • You must be comfortable with validity and reliability of the autoscoring algorithm

• **Real disadvantage**
  – Expensive cost per study (Tonometer)
    • But speed of study interpretation may offset cost
PAT Signal with Standard PSG Signal (OSA)

Attenuation of PAT Signal
Watch PAT 200: Snoring without OSA 30 mins
Watch PAT 200: Severe OSA 10mins
Watch PAT Report

Sleep Staging: How Does It Score Sleep?
PAT and NREM Sleep
PAT Signal Attenuates in REM Sleep

- PAT Attenuation
- Irregular Pulse Rate
- No Change in Pulse Ox

SDB Workshop 2018
How Good is the PAT Algorithm for Scoring Sleep Stages?

**Table 1**—Overall agreement of the PAT recorder device with PSG for detection of stage (wake/light sleep/deep sleep/REM sleep) in subgroups of subjects categorized by OSA severity (epoch-by-epoch comparison).

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<th>No</th>
<th>Sleep Stages Agreement, %</th>
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<td>Normal</td>
<td>38</td>
<td>65.4 ± 9.5</td>
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<tr>
<td>Mild</td>
<td>54</td>
<td>64.7 ± 6.6</td>
</tr>
<tr>
<td>Moderate</td>
<td>82</td>
<td>64.2 ± 7.8</td>
</tr>
<tr>
<td>Severe</td>
<td>53</td>
<td>70.6 ± 10.4</td>
</tr>
<tr>
<td>All</td>
<td>227</td>
<td>66.0 ± 8.8</td>
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Agreement is defined as the number of epochs where agreement exists in any specific state divided by the total number of epochs (shown as mean ± SD).

Only moderate agreement between light, deep and REM sleep in all groups.

Better agreement in TST between PAT and PSG.

## Watch PAT Supporting Data

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<td>• AHI ≥ 5: Limited data specificity 0.43 (95% CI: 0.22 to 0.66)</td>
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<td>• AHI ≥ 15: Sensitivity 0.92 to 0.96 and specificity 0.77 to 1.00</td>
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<td>• AHI ≥ 30: Sensitivity 0.92 (0.62 to 1.00) and specificity 0.82 (0.57 to 0.96)</td>
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<td>Yalamanchali et al</td>
<td>• RDI and AHI: r = 0.889 (95% CI, 0.862-0.911) P &lt; 0.001</td>
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### Conclusion:
- Strong correlation between PAT and PSG for respiratory parameters

Yalamanchali S et al. JAMA Otolaryngol Head Neck Surg 2013
Watch PAT Supporting Data

- **WatchPAT** is adequate for diagnosing OSA
  - (3 IA and 4 IIA studies)

- Devices that measure nasal pressure **plus** effort are adequate to diagnose OSA
  - Embletta and Stardust II

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Pulse Oximetry

• How does it work?
  – Compares how much red light and infra red light is absorbed by the blood. Depending on the amounts of oxy Hb and deoxy Hb present, the ratio of the amount of red light absorbed compared to the amount of infrared light absorbed changes.

• AASM recommendations for testing:
  – Maximum acceptable signal averaging time of ≤ 3 seconds at a heart beat of 80 beats per minutes
Pulse Oximetry: Why Consider for OSA Testing

• ODI and hypoxic burden may be better predictors of cardiovascular risk than AHI for patients with OSA and CSA

• Limited outcomes data demonstrate similar outcomes to PSG based management strategy in high risk groups
  – Mulgrew 2007
  – Chai-Coetzer 2013

• Reduced cost

Chai-Coetzer C et al. JAMA 2013;309:997-1004
Can HSAT be Used to Diagnose CSA?

- PSG considered the standard for CSA diagnosis
- Type 3 HSATs should be able to diagnose CSA
HSAT For CSA?

• Limited data validating type 3 HSATs against PSG for CSA diagnosis
  – No randomized controlled outcomes data for HSAT for CSA
• Prospective cohort data demonstrates type 3 HSAT can identify OSA and CSA in patients with CHF and may predict cardiovascular outcomes:
  – 963 patients with chronic stable HF-REF (NYHA ≥ 2)
  – Type 3 unattended in-hospital HSAT
  – Results:
    • Moderate to severe SDB associated with increased mortality
      – Mostly CSA (48%) vs OSA (31%)
    • AHI was not an independent risk factor for death
    • Risk of death was independently associated with hypoxic burden (T90)

Watch PAT for CSA Detection

• WatchPAT Central Plus™ is FDA cleared for the detection of CSA
  – Chest Plus sensor to detect respiratory variation as well as snoring and body position
  – PAT upstroke

• Validated in 32 patients with CHF
  – Simultaneous PSG and Watch Pat
  – Sensitivity = 0.83 and specificity = 0.85 for CSA
  – Cheyne stokes breathing % vs PSG = 0.94

• Additional sleep parameters:
  – pAHlc
  – %CSA (not FDA cleared)
Forced Oscillation Technique

Obstructive Apnea  Obstructive Hypopnea  Normal Breathing

CPAP=4 cmH₂O  CPAP=8 cmH₂O  CPAP=12 cmH₂O

V' (l/s)

P es (cmH₂O)

R es (cmH₂O.l.s⁻¹)

TIME (s)

Navajas, D et al. AJRCCM 1998;157:1526-30
FOT Better for Central Apnea Detection

Apnea – Determined when there is a >75% reduction in airflow for more than 10 seconds.

CSA detected using Forced Oscillation Technique

CSA Detection:
- Sensitivity: 0.99
- Specificity: 0.89
- Accuracy: 0.95

Armitstead J et al. Whitepaper. Resmed Science Center 2010
CSA Diagnosis Summary

• PSG remains the gold standard for diagnosing CSA
  – Central hypopnea detection may still be unreliable

• More data required for HSAT devices
  – Type 3 HSAT (T90) may help predict cardiovascular outcomes in patients with CHF
  – Watch PAT FDA cleared for CSA detection
    • More validation data and outcomes data needed

• FOT may aid in the diagnosis of CSA
Hypoventilation: AASM Scoring Manual

• Monitoring hypoventilation is **optional**
• If monitoring for hypoventilation, recommended monitoring includes:
  – Diagnostic study: Arterial PCO₂, transcutaneous or end-tidal CO₂
  – PAP titration: Arterial PCO₂ or transcutaneous CO₂
  – ****DON’T USE ETCO₂ with PAP****
  – Best monitoring device or method (ETCO₂, etc..) **not** clear
• Hypoventilation is scored if **either** of the following occur:
  – Increase of PCO₂ or surrogate to value > 55 mm Hg for ≥ 10 minutes **or**
  – Increase of PCO₂ or surrogate during sleep (in comparison to awake supine value) to a value > 50 mm HG for ≥ 10 minutes
• Other things to know:
  – Persistent oxygen desaturation alone is **not** sufficient
  – Duration of event **not** defined
SBD Diagnosis Summary

• OSA
  – PSG is the standard to diagnose OSA across disease severity, regardless of comorbid conditions
  – HSATs are adequate to diagnose OSA in patients with a high pretest probability of uncomplicated moderate to severe OSA
    • HSATs can be used as part of a strategy to diagnose and manage patients with OSA

• CSA
  – PSG still the standard

• Hypoventilation
  – ABG with or without PSG with CO₂ monitoring
Thank You