The Nuts and Bolts of PAP - Including CPAP Tracking

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Indications for CPAP - ACCP Consensus Statement


- OSA patients with AHI >30 events/hour regardless of symptoms
- OSA patients with AHI of 5-30 events/hour with associated symptoms:
  - Excessive daytime sleepiness
  - Impaired cognition and mood disorders
  - Insomnia
  - Cardiovascular diseases:
    - HTN, ischemic heart disease and CVA

Clinical Algorithm for Initiating CPAP at the Penn Sleep Center

Patient seen in clinic or PSG ordered → PSG reviewed in clinic

Nurse sees patient in 1 month with CPAP data → Physician sees patient in 3 months with CPAP data
CPAP Units Do Not Have to Look Like Medical Equipment

State-of-the-Art CPAP Units
- DeVilbiss
- F&P Icon
- ResMed S9
- Respironics System One

E-A-G-L-E-S

2014 World Champions or Last Place?
Z1 CPAP (Human Design Medical LLC) Travel CPAP

• Features:
  – Very quiet < 26 decibels
  – Very light weight at 10 oz.
  – Backlit LCD display to follow the status of CPAP
  – Data Recording & Software
  – Ramp Feature
  – ZBreathe Pressure Relief
  – Can be used with the optional battery or regular AC power

Introduction to CPAP: What to tell the Patient

• Safer than using a medication
• Not a breathing machine - the patient will not die if s/he comes off the unit
• Pneumatic splint to open the airway - it is not oxygen
• Noise is much less than snoring - white noise
• Only need to sleep with it
• Consider a desensitization program
  – Get used to it - watch TV with CPAP on
  – Take pictures of yourself

CPAP Interfaces

• No controlled trials demonstrating differences in efficacy between various CPAP interfaces
• Nasal interfaces
  – Nasal masks
  – Nasal pillows/direct nasal interfaces
• Full face masks
• Hybrid masks - Liberty
• Mouthpieces - Oracle, SomnuSeal

ResMed Swift Nasal Pillows

• Light
• Easy fit
• Quiet – Small vent holes
• Compact
**ResMed Mirage Swift Nasal Pillows System**

- Headgear ensures fit
- Light 2.5 oz. (70 grams)

**Philips Respironics GoLife for Women**

**Phillips Respironics Wisp Hybrid Mask**

**ResMed’s AirFit P10 Nasal Pillows**

- The AirFit P10 is similar to the Swift™ FX mask, but is approximately 50% quieter and 50% lighter
- The AirFit P10 has three pieces
ResMed Swift FX Nano

- Headgear that does not require a rigid frame or forehead support
- Comes with a nasal cushion
- Ball joint elbow that moves during sleep
- Can wear glasses while on therapy

InnoMed Technologies
Nasal-Pap Freestyle

- Can be worn with or without headgear
- 7 sizes
- No pressure points on the face
- Anatomically shaped for the nostril

Nuance Pro Gel Pillows - Philips Respironics

Gel padded frame and headgear holds mask in place

Phillips Respironics Comfort Gel Nasal Mask

- Gel interface
- Dual layer cushion
DeVilbiss EasyFit Nasal Mask

- The EasyFit Nasal Mask was designed by utilizing computer analyses of facial characteristics from 50,000 individuals.
- Identifying consistencies between most of these facial profiles attributed to the development of the scallop-shaped cushion.
- It is a lightweight and durable nasal mask.

ResMed Mirage Activa Nasal Mask

- May be useful for patients with a beard or a mustache.
- Inflatable chamber expands and contracts during therapy.
- Almost floats on the face.
- Helps prevent leaks while minimizing pressure on face.

Phillips Respironics Easy Life Nasal Mask

- Lightweight design delivers auto seal technology.

F&P Eson Nasal CPAP Mask with Headgear

- Customizable & stable fit for all sizes.
- Small & lightweight.
- Adapts to nighttime movement using a ball & socket elbow at bridge of mask’s nose.
Phillips Respironics Amara Gel Full Face Mask

Phillips Respironics ComfortGel Full
- Forehead cushion
- Replaceable gel cushion
- Replaceable silicone flap

ResMed Mirage Quattro & Mirage Liberty
- Quattro FFM
- Liberty mask - good for claustrophobia
**ResMed Quattro Air**

One of the lightest full face masks

**Phillips Respironics FitLife Full Face Mask**

**Fisher & Paykel Oracle 2 - Oral Mask**

- As effective as nasal masks
- No headgear needed
- Increased/decreased comfort?
- Nasal plugs
- Use with a heated humidifier
- Increased salivation
- Useful for claustrophobia?

- Useful for patients with mouth opening?
- Useful for sinusitis?

**Discover Medical SomnuSeal CPAP Mask**

- SomnuSeal is a new oral CPAP mask
- Less pressure required
- Use 4-6 cm of H₂O
- Designed for patients unable to tolerate other CPAP masks
- Fits between gum and teeth
- Not available yet in US
- Use humidifier at highest level
- ? salivation issues
Pediatric CPAP

How do you Treat Rainout in CPAP Tubing?

- Decrease humidification which may be difficult in the winter
- Add/switch to heated tubing
  - Respironics system one 60 Series
  - ResMed ClimateLine heated tubing for all S9 CPAP units
- Tube buddy or snugglehose to keep the tubing warm to prevent condensation

What is a SnuggleHose?

- SnuggleHoses are warm, soft covers for CPAP hoses
- They are hypo-allergenic and decrease condensation from humidifiers
- They may decrease nighttime awakenings due to a cold hard hose touching your skin
- They come in a variety of colors and prints
- Available in 6, 7, 8, 9 and 10 foot lengths
How to Determine the Optimal CPAP Setting?

- With HST use CPAP tracking systems
  - Examine the residual AHI to determine if CPAP setting is adequate
- Use polysomnography to determine the optimal pressure (5 - 20 cm H$_2$O)
  - Abolish apneas and hypopneas
  - Abolish snoring and related arousals
  - Maintain O$_2$ saturation > 90%
  - Reduction in total arousal index
    - In all positions and during REM sleep

CPAP Problems and Adherence

- Patient acceptability
- Patient acceptability
- Patient acceptability
- Compliance 50 - 60%
- Average nightly use 4.8 hours - not so bad!
- Approximately 35% of patients "love" CPAP, 50% struggle with CPAP but eventually tolerate it and about 15% "hate" CPAP and never use it
- We are able to track CPAP use

Bilevel Positive Airway Pressure

- Several different commercially available bilevel systems
- Independent regulation of inspiratory (IPAP) and expiratory (EPAP) airway pressures
  - Lower expiratory pressures
  - May be useful for patients who have difficulty with exhalation or chest pain with CPAP
  - Algorithms to adjust pressures empiric
    - Increase EPAP or IPAP or both?
    - Role of IPAP and EPAP in abolishing apneas needs to be studied
- Auto-BiPAP systems - how do they work?
  - The pressure differential between IPAP and EPAP is fixed (lowest setting is 4 cm of water)
Auto-CPAP

- Newest modification in CPAP systems
- These units adjust the CPAP throughout night rather than delivering one fixed pressure
- Optimal CPAP varies during night:
  - Positional changes
  - Sleep state dependent changes REM vs. NREM; effects of sleep deprivation
  - Alcohol or sedative effects
  - Effects of upper airway infections/colds
  - Useful for bariatric surgery patients
  - Becoming standard with HST

CPAP Adherence Tracking Systems

- How do they work? Well they are all different
- Typically they track adherence, leak and efficacy
  - Are the data reliable or reproducible? - for adherence but not robust for leak or efficacy
- What are the “best” CPAP tracking systems?
  - Good question???
- Are there any guidelines on how to use these systems? Yes

An Official American Thoracic Society Clinical Statement:
CPAP Adherence Tracking Systems: the Optimal Monitoring Strategies and Outcome Measures


CPAP Adherence Tracking Systems

- CPAP adherence tracking systems are virtually used by all sleep physicians who take care of patients with apnea
- Requirement for Medicare CPAP payment
- While CPAP adherence tracking systems have not been extensively tested, their use intuitively makes sense
- It is possible that CPAP adherence monitoring is a nice “supplement” to clinical decision making but does not fundamentally change results
- There are essentially no data to support the use of these tracking systems and the algorithms for mask leak and residual AHI have not been validated
Tracking CPAP Adherence is Important!

- Patient self-report of hours of use
  - No correlation with actual hours of use
  - Routinely overestimate usage
- Hour meter on the CPAP device
  - Meter hours/number of days
  - Major limitation: does not provide true pattern of use
  - Cannot detect if the mask was applied

What Type of CPAP Adherence Equipment to Use?

- Philips Respironics and ResMed have been the leaders in developing these CPAP tracking systems but Fisher & Paykel and DeVilbiss both have new systems
- Smart Card technology has been the primary means of obtaining data
- New developments:
  - Wireless technology may be the future
  - SD (secure digital) cards - photocards
  - Measures of heart rate, oxygen saturation
  - High definition flow signals
Excellent Compliance

Tracking CPAP Adherence

- In general these systems track adherence reliably
- Patients may fail to insert the “smart card” into the CPAP unit
- They may have a faulty card
- Some machines only track CPAP use for limited periods, resulting in confusion if data are downloaded for a period that exceeds the storage capacity of the recording system
- They may be unable to provide individualized data if the CPAP device/card was used by multiple patients
- The flow sensor can malfunction resulting in erroneous adherence
- Should time in a “large” leak be counted as time at an effective pressure?

What Level of Residual AHI Matters?

Event Detection from Device vs. PSG

- No accepted definition for an appropriate cutoff for the residual AHI (AHI < 5 events/hour); long term effects of residual AHI not known; AH1 is the wrong terminology
- These devices all have different algorithms to determine apneas and hypopneas
  - Apnea more robust than hypopnea?
  - Mouth leak may be a problem
- Hypopnea on an in-lab PSG is determined with an EEG arousal or oxyhemoglobin desaturation
- These devices rely only on flow patterns (pneumotach) to estimate the residual apnea/hypopnea index
- Averaged data over many nights/months. Examine data during the last week
**CPAP Unit Respiratory Event Detection: Can we Trust the Residual AHI?**

- Very little data - we need larger studies from multiple sites examining outcomes with residual AHI
- In the meantime, caution should be used in interpreting OSA resolution from such data reports
- High or low values more likely to be valid than moderate values
- Apneas appear more reliable than hypopneas?
- Terminology for residual AHI assessment should be standardized, it should be reported as residual \( \text{AHI}_{\text{FLOW}} \)

**Leak Measures**

**Respironics**
- Average max leak
- Average 90% leak
- Average leak
- Average large leak

**ResMed**
- Median leak
- 95% percentile
- Maximum leak

Most units measure liters/minute but the leak can also be reported as liters/second

**What Metric of Mask Leak Should be Used?**

- Intentional leak
- Max leak
- Large leak
- Unintentional leak
- Average 90% leak
- Median leak

Leak depends on mask and pressure
Quantifying Mask Leak

- What is a clinically significant mask leak?
  - Respironics: large leak for > 1 hour?
  - ResMed: > 24 liters/minute (95th percentile); > 36 L/minute for a full face mask (95th percentile)
  - DeVilbiss unit a mask leak of > 95 liters/minute
  - Fisher & Paykel a mask leak > 60 liters/minute
  - There may be no leak threshold that is “clinically meaningful”, as even a small leak directed into a patient's eyes can be problematic
  - Averaged data over weeks/months
  - May be secondary to leaking around the mask or through the mouth (with a nasal mask)

CPAP Tracking Systems - Take Home

- Adherence - data mostly reliable
- Events (residual apnea/hypopnea) - data not robust but ends of the spectrum may be useful focus on apneas (change terminology to AHI\textsubscript{Flow})
  - What residual AI or AHI is important?
- Leak - data not robust but ends of the spectrum may be helpful; what level of a large leak matters?
- No studies as of yet that show tracking adherence improves outcomes
- Technology not science is driving clinical management

Tracking CPAP Adherence

- 10 Years ago - smart card data
- 6 Years ago - modems
- Today - SleepMapper and cloud based data (U-Sleep)
  - SleepMapper (Philips Respironics, System One devices): an interactive web-based application that allows the patient to monitor their own compliance
    - SleepMapper is the “patient’s version” of Encore Anywhere
    - Patients sign up on www.sleepmapper.com or download from app store “SleepMapper”
  - U-Cloud-based care management software
    - Daily upload from wireless modem
    - Compatible with ResMed, F&P, DeVilbiss
SleepMapper is a free mobile app and web-based system that provides personalized feedback for sleep apnea therapy. SleepMapper links to a provider’s EncoreAnywhere database.

When a patient creates a SleepMapper account they will have access to the following (either via internet or smartphone/tablet app):

- Daily feedback on AHI, CPAP hours and mask leak
- 2 weeks worth of trend information on AHI, CPAP hours and mask fit (leak)
- Dynamic messaging
  - Reminds patients to clean equipment
  - Alerts patients when they need to fix leak issues
  - Directed to specific troubleshooting info
  - Motivational information
  - Educational videos

The SleepMapper application uses Bluetooth to sync with System One, but if the patient does not have a compatible smartphone, all the data can be downloaded from the machine’s SD card onto a computer, or it can interact with a modem if it is already installed.

Cloud-based care management software
  - Daily upload from wireless modem
  - Compatible with ResMed, F&P, Devilbiss

Collects and records detailed individual patient data
  - Residual AHI, leak, average pressure, hours of use, vibratory snore, etc

Data can be exported into PDF and Excel
Umbian’s U-Sleep

- Includes a patient portal accessible through web, iPhone, iPad, Android

Adherence Data Derived from CPAP Tracking Systems

<table>
<thead>
<tr>
<th>Date ranges of device usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of nights the CPAP was used</td>
</tr>
<tr>
<td>Total number of nights the CPAP was not used</td>
</tr>
<tr>
<td>Percentage of nights with CPAP usage</td>
</tr>
<tr>
<td>Percentage of nights with CPAP usage &gt;= 4 hours a night</td>
</tr>
<tr>
<td>Percentage of nights with CPAP usage &lt; 4 hours a night</td>
</tr>
<tr>
<td>Average usage on nights when CPAP was used</td>
</tr>
<tr>
<td>Average usage on all nights</td>
</tr>
</tbody>
</table>

Event Detection Algorithm

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Apnea event detection</th>
<th>Hypopnea event detection</th>
</tr>
</thead>
<tbody>
<tr>
<td>DeVilbiss Healthcare IntelliPAP unit (SmartCode Remote Data Retrieval System)</td>
<td>A reduction in a flow signal of &gt; 90% of the baseline flow for 10 seconds</td>
<td>A reduction in a flow signal of &gt; 50% of the baseline flow for 10 seconds</td>
</tr>
<tr>
<td>Fisher &amp; Paykel Infosmart software</td>
<td>&gt; 80% reduction in flow relative to a baseline determined from previous breaths</td>
<td>&gt; 40% reduction in flow relative to a baseline determined from previous breaths</td>
</tr>
</tbody>
</table>

CPAP Adherence Tracking Systems: the Optimal Monitoring Strategies and Outcome Measures (Schwab et al, AJRCCM 188, 613-620, 2013)
### CPAP Mask Leak Measurements

<table>
<thead>
<tr>
<th>CPAP Manufacturer</th>
<th>How Leak is Measured</th>
<th>Large Leak Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phillips Respironics</td>
<td>Intentional leak subtracted from total flow</td>
<td>Leak condition where the leak level exceeds a pre-set “flow vs. pressure” curve (the averaged leak through all mask exhalation ports at various pressure)</td>
</tr>
<tr>
<td>ResMed</td>
<td>Unintentional leak (device flow-intentional leak) + mouth leak</td>
<td>95th percentile leak (&lt; 24 liters per minute with nasal interface and &lt; 36 liters per minute with full face interface)</td>
</tr>
<tr>
<td>Fisher &amp; Paykel</td>
<td>Total leak, including mask and exhaust flow from mask</td>
<td>A leak value of &gt; 60 liters per minute</td>
</tr>
<tr>
<td>DeVilbiss Healthcare IntelliPAP</td>
<td>Records high leak flow time as a percentage of the time the leak was above 95 liters per minute</td>
<td>A leak value of &gt; 95 liters per minute</td>
</tr>
</tbody>
</table>