WSS Fall 2018

Advanced Algorithms - Clinical Applications

• Average Volume Assured Ventilation (AVAPS)
• Auto Servo Ventilation (SV)

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Objectives

• Differentiate between BiPAP AVAPS and BiPAP autoSV Advanced
• Identify the patient population that will benefit from BiPAP AVAPS
• Describe the titration protocol for BiPAP AVAPS
• Discuss why the patient population that will benefit from BiPAP AVAPS will not benefit from BiPAP autoSV Advanced

Best Match

Non-Invasive Ventilation

Consensus Conference

"...in patients with neuromuscular disease ... recent reviews have cited the advantages of pressure targeted devices for comfort and their ability to compensate for leaks."

"Pressure targeted systems are not able to guarantee a minimum minute ventilation."

BiPAP AVAPS Patient Types
AVAPS is a feature that always drives the BiPAP unit to a set tidal volume. It is used for patients with changing respiratory needs.

**Sleep Disordered Breathing and Hypoventilation**

*Prevalence of obesity and hypoventilation*

**Presidential Trivia**

Which US president suffered from sleep apnea and obesity hypoventilation syndrome?

"I have lost that tendency to sleepiness which made me think of the fat boy in Pickwick. My color is very much better and my ability to work is greater."

William Howard Taft
27th President of the United States
June 28, 1909

Thomas Nast’s drawing of Fat Joe from Charles Dickens’ "The Pickwick Papers."

**Obesity Hypoventilation Syndrome: Epidemiology**

- Prevalence of obesity: ~20 to 30%
- Prevalence among OSA: 10 to 20%
- Prevalence among adult obese: 10 to 20%
- No clear ethnic or racial predominance

Self-reported obesity by state.

*Obesity Hypoventilation Syndrome: Epidemiology*  

*Self-Reported Obesity by State*  
The data used with permission from Dr. Moklesi"
Epidemiology

Data from Laaban JP, Chailleux E. Daytime hypercapnia in adult patients with obstructive sleep apnea syndrome in France, before initiating nocturnal nasal continuous positive airway pressure therapy. Chest 2005;127:710–5; and Mokhlesi B, Tulaimat A, Faibussowitsch I, et al. Obesity hypoventilation syndrome: prevalence and predictors in patients with obstructive sleep apnea. Sleep Breath 2007;11:117–24. The data from Italy were provided by Professor Onofrio Resta from the University of Bari, Italy.

Consequence of OHS

- Increases
  - Daytime symptoms
  - Traffic incidents
  - Morbidity
  - Cardiovascular morbidities
  - Acute submission of respiratory failure
  - Pulmonary hypertension
  - Mortality
  - 20 to 70%
  - Decreases quality of life

Treatment of Obesity Hypoventilation Syndrome

OHS vs. Kyphoscoliosis Treatment

Changes in Physiological Outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>OHS base</th>
<th>OHS w/NIV</th>
<th>Kypho base</th>
<th>Kypho w/NIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>PO2</td>
<td>51 ± 10</td>
<td>64 ± 11</td>
<td>55 ± 6</td>
<td>65 ± 5</td>
</tr>
<tr>
<td>PCO2</td>
<td>58 ± 10</td>
<td>45 ± 5</td>
<td>59 ± 11</td>
<td>45 ± 4</td>
</tr>
<tr>
<td>pH</td>
<td>7.36 ± 0.04</td>
<td>7.41 ± 0.03</td>
<td>7.35 ± 0.03</td>
<td>7.38 ± 0.02</td>
</tr>
<tr>
<td>FEV1</td>
<td>60 ± 12</td>
<td>61 ± 10</td>
<td>27 ± 11</td>
<td>30 ± 12</td>
</tr>
<tr>
<td>FEV1/FVC</td>
<td>80 ± 13</td>
<td>81 ± 10</td>
<td>84 ± 8</td>
<td>85 ± 11</td>
</tr>
<tr>
<td>TLC</td>
<td>80 ± 13</td>
<td>87 ± 15</td>
<td>48 ± 8</td>
<td>49 ± 9</td>
</tr>
</tbody>
</table>

Bi-level with Volume Assured

- Acts primarily as a bi-level pressure support device but is able to provide a constant tidal volume
- Automatically adjusts the pressure support level to maintain a consistent tidal volume
- IPAP will automatically increase or decrease to maintain set tidal volume
AVAPS®

- Automatically adjusts the pressure support level to maintain a consistent tidal volume
- IPAP will automatically increase or decrease

Clinical Benefits of Bi-Level with Volume Assured

- Maintains ventilatory support and tidal volume during
  - progressive ventilatory changes of the patient
  - positional changes during sleep
- Alarms to indicate that tidal volume is not being maintained

Clinical Study

Average volume-assured pressure support in obesity hypoventilation: A randomized crossover trial

- RCT with crossover design of OHS who failed CPAP (failure defined as RDI>10 and TcCO₂>45 mm Hg)
- N=10 (mean age: 53.5; BMI: 41.6; PaCO₂ 47.4; RDI 74)
- Randomized to BiPAP S/T or BiPAP AVAPS and after six weeks patients were crossed over to the other arm

Results - PtcCO₂ during Sleep

Storre JH et al, Average volume-assured pressure support in obesity hypoventilation: A randomized crossover trial Chest 2006; 130:815

Conclusions

- Bi-level ventilation improved sleep quality in patients with OHS
- "The addition of volume assurance (i.e., AVAPS) to BPV-S/T therapy resulted in a significant decrease of PtcCO₂, thus normalizing PtcCO₂ during sleep"

Suggested Titration Protocol for BiPAP® AVAPS

1. Set Tidal Volume target
2. Set IMPPmax at 8 cm H₂O
3. Set IMPPmin at 25 cm H₂O
4. Set EPAP at 4 cm H₂O
5. Set Rate at 8-10 BPM or 2 BPM below the patient's spontaneous rate
6. Set I-Time at 1.5 seconds or patient comfort
7. Set Rise time at 2 or 3 or patient comfort

Three ways to choose a starting tidal volume with AVAPS

1. MD suggestion
2. Patient Comfort
3. Ideal body weight: 8 ml/kg

*AVAPS suggested tidal volume settings based on height and ideal weight

Height (inches) 59 61 63 65 67 69 71 73 75
Ideal Weight (kg) 52.0 55.5 59.0 62.5 66.5 70.5 74.5 78.5 83

Average Volume-Assured Pressure Support in Obesity Hypoventilation

Average volume-assured pressure support in obesity hypoventilation: A randomized crossover trial

Storre JH et al, Average volume-assured pressure support in obesity hypoventilation: A randomized crossover trial Chest 2006; 130:815
Suggested Titration Protocol for BiPAP AVAPS

Observe for Events

Obstructive Events*:
- Increase EPAP by 1 cm H<sub>2</sub>O
- Hypopneas, RERAs, Snoring

Respiratory Events**:  
- Inadequate Tidal Volume: 
  - increase the Tidal Volume target  
- Inadequate Respiratory Rate:  
  - increase RR by 2 BPM  
- Inadequate Oxygenation:  
  - increase EPAP  
  - Wait 5 minutes

*Obstructive Event
**Other
***Respiratory Event
Appearance of, or worsening of, hypoventilation during sleep

Clinical Case Study
OHS and Volume Assured

Case Study: Volume assured and obesity hypoventilation
- 55 year old male
- BMI = 35
- Settings: S/T mode + volume assured ventilation
  - VT = 550 ml
  - IPAP min = 7 cm H<sub>2</sub>O
  - IPAP max = 25 cm H<sub>2</sub>O
  - EPAP = 6 cm H<sub>2</sub>O
  - Backup rate = 12 BPM

Decrease in IPAP over time
Stable tidal volume with a target of 550 ml

Case Study: Volume assured and obesity hypoventilation
- Average IPAP at 9 cmH<sub>2</sub>O
- IPAP increases at night correlating with sleep stages and body position
Stable tidal volume

Pressure support need decreased with time
Very good compliance
Progressive evolution to a CPAP mode
Still needs high pressures for deep sleep stages and to compensate for his body position
Placed back on S/T mode with volume assured ventilation

**Conclusion**

**Servo Ventilation**

**Servo ventilation patient types**

**BiPAP autoSV Advanced: Automatic Servo Ventilation**

- Treatment for complicated breathing patterns such as Central apnea, Complex apnea and Periodic Breathing such as CSR
- Provides non-invasive ventilatory support to treat adult patients with OSA and respiratory insufficiency caused by central and/or mixed apneas and periodic breathing.
- Built with existing RI proven technologies
  - Digital Auto-Trak™ Algorithm that targets peak flow
  - Encore Pro/Anywhere and Care Orchestrator for patient reporting

**BiPAP autoSV Advanced: Automatic Servo Ventilation**

- Targets peak flow over a 4 min. moving window
- Adjusts inspiratory pressure breath to breath when necessary (to achieve targeted peak flow)

**BiPAP autoSV Advanced: Automatic Servo Ventilation**

- Automatically adjusting EPAP
  - Titrates to eliminate obstructive component
  - Distinguishes between obstructed and clear (open) airway
  - Enhanced automatically calculated back-up breath rate
    - Based on patient’s spontaneous breath rate OR
    - Standard rates of 4 – 30 bpm
Link between sleep apnea, hypertension and cardiovascular diseases (CVD)

OSA and Hypertension

The incidence of hypertension increases with severity of OSA. Most importantly, compared with controls, the risk for new-onset hypertension was greater among all groups of patients with OSA who were untreated.


Cardiovascular effects of OSA

Repetitive obstructive events expose the circulatory system to stimuli that may contribute to the progression of CVD.

- **Negative intrathoracic pressure**
  - Increases:
    - left ventricular transmural pressure
    - venous return
    - right ventricular afterload
    - likelihood of atrial arrhythmias
  - Reduces:
    - stroke volume and cardiac output

Autonomic dysregulation

- Sympathetic excess
- Parasympathetic withdrawal

Kasai et al, Sleep Apnea and Cardiovascular Disease: A Bidirectional Relationship, Circulation, 2012

OSA and Atrial Fibrillation

OSA is common in patients with atrial fibrillation (AF)
- The adjusted odds ratio for the association between AF and OSA is 2.19

Patients with untreated OSA have a higher recurrence of AF after cardioversion than patients without OSA
- Appropriate treatment with continuous positive airway pressure (CPAP) is associated with lower recurrence of AF:
  - 82% recurrence in untreated OSA
  - 42% recurrence in treated OSA with CPAP


Cardiovascular (CV) effects of CSA

CSA is more likely a consequence, not a cause, of heart failure
- Can initiate further deterioration in cardiovascular function
- Sympathetic Nervous System Activation is increased
- Does not have the extreme effects of negative intrathoracic pressures like OSA

Kawat et al, Sleep Apnea and Cardiotoxic Disease: A Bidirectional Relationship, Circulation, 2012
Impact of untreated OSA

Cardiovascular mortality and morbidity in patients with OSA

- Total sample size = 1651 men, over 10 years
  - 264 normal (control group)
  - 377 snorers (AHI <5)
  - 403 untreated mild to moderate OSA (AHI 5 to 30 without EDS)
  - 372 untreated severe OSA (AHI >30 or AHI >5 with EDS)
  - 372 severe OSA with CPAP treatment of OSA (AHI >30, CPAP >4 hrs/day)

- CPAP compliance objectively measured
- Study outcomes: fatal and non-fatal cardiac events

Study Results

CV events over 10-year period

<table>
<thead>
<tr>
<th></th>
<th>Fatal events</th>
<th>Non-fatal events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Snorers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AHI &lt;5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AHI 5 to 30 without EDS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AHI &gt;30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AHI &gt;5 with EDS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AHI &gt;30, CPAP &gt;4 hrs/day</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Study Conclusion

1. Patients with severe OSA who were untreated had a significant increase in CV events (both fatal and non-fatal events) after 10 years: risk factor 2.87 higher than normal

2. Patients with severe OSA had a significant reduction in CV events when their OSA was effectively treated (>4 hours/night) with CPAP

Prevalence of OSA in patients with CVD

- General population
- Heart Failure patients
- Patients with CAD
- Patients with Myocardial Infarction

Treatment with Servo Ventilation

- Stabilize the unstable flow pattern
- Deliver pressure support only when needed
- Trigger mandatory breaths when needed
- Provide efficient pneumatic splint
The limitations of CPAP treatment in CSA and CSR

Although CPAP was able to reduce AH1 and increase LVEF, the CANPAP trial did not demonstrate a beneficial effect of CPAP on morbidity or mortality in patients with central sleep apnea and HF.

CPAP only produced a 53% fall in CSA.

Bradley TD et al. CPAP for CSA and Heart Failure, N Engl J Med, 2005

Successfully reducing the number of central breathing abnormalities during sleep may decrease their short- and long-term impact on the patient prognosis.

Suppression of CSA in HF patients is the key to improving survival. Since only ~50% of patients had effective suppression of CSA on CPAP, other treatment modalities may be required in this patient group.

Arzt M et al. Suppression of CSA by CPAP in heart failure, Circulation 2007

CompSAS: NPPV vs. Servo Ventilation

Servo ventilation for central sleep apnea

Servo ventilation
- Effectively suppresses CSA in all patients studied (approximate 90% reduction)
- Suppresses central, periodic, and mixed respiratory disturbances more effectively than CPAP
- Better compliance observed when compared to CPAP
- Improves quality of life and left ventricular ejection fraction (LVEF) vs. CPAP

Servo ventilation, which provides both a minimum pressure to hold the airway open and a precisely calculated ventilatory assist to minimize cyclic hypoventilation and hyperventilation, has emerged as a leading treatment.

Servo ventilation in CompSAS

"In patients with CompSAS, Servo ventilation was the most effective therapy for normalizing breathing and sleep parameters."

"Servo ventilation, which provides both a minimum pressure to hold the airway open and a precisely calculated ventilatory assist to minimize cyclic hypoventilation and hyperventilation, has emerged as a leading treatment."
Clinical Case Study
70 yr. old male with atrial fibrillation and daytime sleepiness

Patient background and PMH
- Patient referred to sleep center for evaluation after completion of ESS with a score of 13 out of 24
- PMH
  - 70 yr old male
  - BMI 27 kg/m²
  - Atrial fibrillation
  - s/p pacemaker implant
  - 2+ pitting edema in legs
- Medication list
  - Lasix QD
  - Warfarin

Diagnostic sleep study results

<table>
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<tr>
<th>Sleep parameters</th>
<th>Diagnostic study</th>
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</thead>
<tbody>
<tr>
<td>Sleep efficiency</td>
<td>73%</td>
</tr>
<tr>
<td>Apnea-hypopnea index (episodes/hr)</td>
<td>44</td>
</tr>
<tr>
<td>Central apnea index (episodes/hr)</td>
<td>10</td>
</tr>
<tr>
<td>Obstructive apnea index (episodes/hr)</td>
<td>19</td>
</tr>
<tr>
<td>Hypopnea index (episodes/hr)</td>
<td>14</td>
</tr>
<tr>
<td>Mixed apnea index (episodes/hr)</td>
<td>0</td>
</tr>
</tbody>
</table>

Diagnosis: severe sleep apnea that is both obstructive and central

CPAP Titration – N1 and N2

CPAP of 8 cm H₂O
Strong crescendo-decrescendo patterns with central apnea and hypopneas

CPAP Titration

- Improvement in sleep efficiency with CPAP as compared to baseline
- However, there was a change in the amount of central events that occurred while not in REM sleep
- New study - Servo ventilation titration
Servo Ventilation Titration

10 minute capture
You can see that during the session, the device detected upper airway instability and increased the EPAP automatically.

Servo Ventilation Titration Results

<table>
<thead>
<tr>
<th>Sleep parameters</th>
<th>Servo ventilation study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep efficiency</td>
<td>95%</td>
</tr>
<tr>
<td>Apnea-hypopnea index</td>
<td>3</td>
</tr>
<tr>
<td>Central apnea index</td>
<td>1</td>
</tr>
<tr>
<td>Obstructive apnea index</td>
<td>0</td>
</tr>
<tr>
<td>Hypopnea index</td>
<td>2</td>
</tr>
<tr>
<td>Mixed apnea index</td>
<td>0</td>
</tr>
</tbody>
</table>

Results from user studies are not predictive of results in other cases. Results in other cases may vary.

Servo Ventilation Titration

10 minute capture
You can see during periods of periodic breathing, the pressure support and backup breath rate system helping to correct the patient’s breathing pattern.

Servo Ventilation

Titration Results

- Prescription after this final study:
  - Max pressure: 25 cm H$_2$O
  - PS min: 0 cm H$_2$O
  - PS max: 15 cm H$_2$O
  - EPAP min: 5 cm H$_2$O
  - EPAP max: 15 cm H$_2$O
  - Auto rate
  - Bi-flex setting of 3

Suggested Titration Protocol for BiPAP AutoSV

Patient on CPAP changed to BiPAP AutoSV

- Set EPAP$_{min}$ at 4 cm H$_2$O or patient comfort
- Set EPAP$_{max}$ at 20 cm H$_2$O
- Set PS$_{min}$ at 0 cm H$_2$O or at patient comfort
- Set PS$_{max}$ to 20 cm H$_2$O
- Set Max pressure to 25 cm H$_2$O
- Rate to Auto
- Set Bi-Flex to patient comfort

Bi-level with volume assurance (AVAPS) is NOT recommended for patients with periodic breathing

- Set EPAP$_{min}$ at 6 to 8 cm H$_2$O or patient comfort
- Set EPAP$_{max}$ at highest level attainable
- Set PS$_{min}$ at 0 cm H$_2$O or at patient comfort
- Set PS$_{max}$ to 20 cm H$_2$O
- Rate to Auto
- Set Bi-Flex to patient comfort

Suggested Titration Protocol for BiPAP AutoSV

- Set EPAP$_{min}$ at 6 to 8 cm H$_2$O or patient comfort
- Set EPAP$_{max}$ at highest level attainable
- Set PS$_{min}$ at 0 cm H$_2$O or at patient comfort
- Set PS$_{max}$ to 20 cm H$_2$O
- Rate to Auto
- Set Bi-Flex to patient comfort

Treatment of periodic breathing requires a variable breath-by-breath response system so the patients PaCO$_2$ stabilizes quickly.

- Prevents overshooting or undershooting the PaCO$_2$ breath by breath
- Does not augment the patients tidal volume consistently
- Does not have a quick variable response to changes in tidal volume
- It is designed to adjust and maintain a constant tidal volume with each breath over time
- This benefit is often seen with patients who have slow declines in their ventilatory conditions
Should you use auto Servo ventilation for a neuromuscular disease? NO!

- Would continually reset it is baseline, worsening the hypoventilation
- Normal target continues to decrease – continues to under ventilate patient as the night progresses

Summary

- Sleep Disordered Breathing is associated with
  - Cardiovascular diseases (CVD)
  - Obesity hypoventilation syndrome (OHS)
  - Untreated OSA may increase risk for CV events
- Effective CPAP use can reduce CV events in patients with severe OSA
- Servo Ventilation is the treatment modality for periodic breathing seen in patients with CVD
- AVAPS - Volume assured is the treatment modality for respiratory insufficiency / hypoventilation such as OHS

Thank You!