Fall 2016 Meeting
October 7-8, 2016

Understanding ASV Therapy

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Conflict of Interest Disclosures for Speakers

1. I do not have any relationships with any entities producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients, OR

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<table>
<thead>
<tr>
<th>Type of Potential Conflict</th>
<th>Details of Potential Conflict</th>
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<td>Grant/Research Support</td>
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3. The material presented in this lecture has no relationship with any of these potential conflicts, OR

4. This talk presents material that is related to one or more of these potential conflicts, and the following objective references are provided as support for this lecture:

1.
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Objectives

1) Understand the diagnosis and treatment strategies for central sleep apnea (CSA)
2) Understand the different forms of central sleep apnea
3) Describe how Adaptive/Automatic Servo-Ventilation (ASV) works and treats central sleep apnea
4) Describe the appropriate indications to use ASV
General Principles for Diagnosis

1) Must have clinical symptoms or medical comorbidities to make diagnosis
   - Sleepiness, insomnia, snoring, apneas, awakening with SOB
   - A-fib, CHF, or neurological disorder (such as stroke, MS)
2) Central AHI >5
3) Central apneas and hypopneas >50% of total AHI
4) Not better explained by another sleep disorder
Prevalence of CSA

- 6.5–15% of OSA patients suffer from complex sleep apnea syndrome
- 18% of heart failure patients with OSA develop complex sleep apnea during CPAP titration
- 30% of heart failure patients have Cheyne–Stokes Respiration (CSR)
- 75% of patients on opioids for chronic pain have an AHI > 5
CSA Pathophysiology

- CO2 falls below apneic threshold
- CO2 does not rise as much during sleep
  - CO2 levels during sleep closer to apneic threshold
- Arousals and transitional sleep lead to hyperventilation
- Increased responsiveness of chemoreceptors
  - Heightened ventilatory responses to arousals and CO2 changes
  - Hyperventilation and lowering of CO2
  - Increased sympathetic tone
  - High loop gain
CSA Pathophysiology (cont.)

• Delay in circulation time
  • Leads to longer cycle length in CSB

• Pulmonary irritant receptor stimulation
  • Pulmonary congestion
    • Supine Position: ↑ cardiac filling pressures
  • CPAP over-titration

• Central apneas usually increase through the night
  • Due to increased pulmonary congestion during the night

• Mild airway obstruction possibly contributes
Supine Position
- ↑ cardiac filling pressures
- Upper airway narrowing

Over-titration of CPAP
Central Sleep Apnea Classification

- With Cheyne-Stokes Breathing (CSB)
- Due to a medical disorder without Cheyne-Stokes
- Due to high altitude periodic breathing
- Due to medication or substance
- Primary (Idiopathic)
- Primary of Infancy or prematurity
- Treatment-Emergent (Complex SA)
CSA with Cheyne-Stokes

- Crescendo-decrescendo pattern
- Cycle length >40 seconds (usually closer to 60 seconds)
- Systolic CHF – longer cycle length
- May be a delay in desaturations – adjust when scoring
- Arousals at top of hyperpnea
Cheyne-Stokes, Delayed Desats
Timing of arousals CSB vs other

Eckert, Chest 2007
CSA with Cheyne-Stokes

- Less commonly complain of daytime sleepiness
- Often combination OSA and CSA, and CSA becomes more prominent after CPAP initiated
- Usually absent or minimal in REM, minimal in N3
- May be seen in 25-40% of patients with chronic CHF and 26-50% of those acutely following stroke
- Associated with A-fib, renal failure, daytime hypocapnia
CSA from Medical Disorder

- Usually brainstem lesion
- Stroke
  - May continue in 7% long term
  - Can get Cheyne-Stokes in bilateral lesions
- Multiple Sclerosis
  - Brainstem plaques
- Tumor
- Chiari Malformation
- Multiple System Atrophy
CSA and Stroke
Medullary Astrocytoma
CSA from Medication or Substance

- Suppresses respiratory drive
- Opioids – Methadone, long acting opioids, Suboxone, fentanyl patches
  - Dose dependent
- May improve somewhat over time
- May see ataxic breathing (Biot’s respirations)
- Can also cause hypoventilation and OSA
- Sleepiness often caused by substance, not CSA
Variations of "Biot's Breathing"

Mild

Moderate

Severe

Cluster

300 Seconds

Walker et al, J Clin Sleep Med 2007
Figure 1—Rate ratio for morphine dose equivalent and obstructive apnea, central apnea, and hypopnea indexes; all adjusted for weight, sex, and age. REM refers to rapid eye movement sleep; NREM, non-rapid eye movement sleep.
Primary (Idiopathic) CSA

- Usually have low normal CO2 levels at baseline
- Heightened ventilatory responses to arousals and CO2 changes – chemoreceptors more responsive
  - High loop gain
- Frequent arousals worsen central apnea - usually lower arousal threshold
Treatment-Emergent (complex) CSA

- Obstructive or mixed events on baseline, then predominantly central events on titration
- Often resolved in REM and N3, prominent in N1-N2.
  - Look in REM to see what pressure treats obstruction
- Prevalence: 2-20% on first or second night with CPAP
  - Seen in 15% of SDB population in academic sleep center
  - Seen in 18% of CHF patients
  - Closer to 2% have persistent CSA on chronic CPAP therapy
- Up to 50% of complex SA patients never have good clinical response to CPAP
  - Residual sleepiness, insomnia, arousals
  - CPAP intolerance: “tearing off mask”

Morgenthaler et al, Sleep, 2006
Treatment-Emergent (complex) CSA

- Often low arousal threshold
- Reducing upper airway resistance brings out centrals
- Over-titration can bring out central apneas
- Under-titration can lead to events and arousals which lead to central events
- Bi-PAP often makes it worse
- Arousals from mask leak
- Split night studies are more commonly associated
- Unclear how much will resolve with time
Treatment Options for CSA

• Adaptive Servo-Ventilation (ASV)
• If CHF related
  • optimization of CHF treatment!
  • CPAP if patient is a responder
• Supplemental oxygen
  • Trouble with reimbursement
• BiPAP with fixed backup rate (ST)
  • Usually only if ASV and oxygen not effective
• Hypnotics – decrease arousals
• Positional therapy
• ? Acetazolamide (Diamox)
• Opioid induced – withdrawal of opioids
History of CPAP/ASV

- Early 1980s, Dr Colin Sullivan from Sydney Australia invented CPAP – experiments with vacuum cleaners combined with hand molded face masks
  - Worked with ResCare – later became ResMed
  - Respironics came out with sleep easy machine

- Early-mid 1990s – Respironics invents “BiPAP”

- Mid-late 1990s – ResMed introduces Sullivan Autoset-T which pioneers AUTO titration

- Mid 2000s - Respironics introduce an AUTO Bipap

- 2006 - Resmed comes out with ASV
How does ASV work???
ASV – what does it mean?

• Servo latin root: "to save," "to keep," "to guard," "to watch over"

• Servomechanism: a mechanical or electromechanical system for control of the position or speed of an output transducer. Negative feedback is incorporated to minimize discrepancies between the output state and the input control setting

• Servo: An object that is controlled by feedback signals from the object that it is controlling

• There is a “servo” (the ASV machine) and the “controller” (the person’s breathing).

• controlled loop feed-back system
ASV in once sentence:

Dynamically adjusts pressure support and respiratory rate to stabilize patient’s breathing
Different Machines Work Differently

- **Respironics BiPAP Auto SV Advanced System One**
  - Peak flow measurement – 95% target
  - 4 minute moving window
  - Auto adjusting EPAP
    - Responds to OA, OH, flow limit, snore
  - Biflex
  - EPAP decreases with excessive leak

- **ResMed VPAP Adapt Auto, AirCurve 10 ASV**
  - Minute ventilation – 90% target
  - 3 minute moving window
  - Now auto adjusting EPAP (ASV auto mode)
    - Responds to OA, flow limit & snore
  - “Easy-breath” – syncs with patients breathing
  - no EPR available
  - BR increases with excessive leak
Servo Ventilation Algorithm

On a breath by breath basis peak flow is captured

Peak flow is monitored over a moving 4 minute window

As 1 breath is added, the initial breath falls off

At every point within this 4 minute period an **Average Peak Flow** is calculated

The **Peak flow target** is established around that average and is based on the patient’s needs
VPAP Adapt Estimates Minute Ventilation

- Targets 90% of this calculation
- It averages over a 3 minute moving window
- Peak flow may be the same although minute ventilation is different
Patient exhibits periodic breathing

MV-ASV turned on

A decrease in minute ventilation is rapidly treated by increasing Pressure Support

Pressure Support decreases as minute ventilation returns to target

Pressure Support increases in response to decreasing minute ventilation

Obstructive apnea

Pressure Support increases as minute ventilation drops below the dynamic target during the obstructive apnea

Flow-limited breaths

Pressure Support increases to maintain minute ventilation above target.

Algorithm detects obstructive event as increases in Pressure Support do not stabilize minute ventilation. Once breathing resumes, it increases EPAP in proportion to the severity of the event.

Algorithm detects second obstructive apnea. Once breathing resumes, it increases EPAP to prevent further apneas from occurring.

EPAP increases in response to flow limitation; the EPAP response is smaller than the response to the obstruction because the event is less severe.
BiPAP Auto SV Advanced – Auto EPAP

- Increase 1 cm after 2 events (OA or OH) or 3 snoring events
  - Will wait at least 2 minutes before increasing EPAP again
- Looks every 5 minutes at flow signal and increases EPAP by 1 cm to see if makes a difference in flow limitation (Pro Active Analysis)

Sophisticated Three Layered Algorithm:

Safety Net

Primary Function

- Pro Active Analysis

Apnea

Hypopnea

Flow Limitation

Vibratory Snore

Leak Tolerance
Event classified as an **Obstructed Airway Apnea**

EPAP pressure increased (after 2-OA’s)

No Flow Response!

Backup Breaths
Obstructed Airway

Apnea

12.5 to 13.5
VPAP Adapt Auto EPAP Mode
Auto SV Advanced System One Parameters

- EPAPmin: 4-25 cm H2O
- EPAPmax: 4-25 cmH2O
- PSmin: 0-21 cmH2O (default 0)
- PSmax: 0-21 cm H2O (PS min to IPAP 25)
- Max pressure: 25 cm H2O
- Rate: Auto (8-15), or fixed (4 – 30 BPM)
- Timed Insp (if rate fixed): 0.5 – 3.0 sec (default 1.2 secs)
  - Consider shorter inspiratory time for COPD patients
- Rise: 1 – 6 (100 – 600ms) – longer rise may help with comfort
- Bi-Flex: set to patient comfort (0-3)

Figure 3-2 Triggering and Cycling when the Back-Up Rate is Off
ResMed VPAP Adapt Auto Parameters

- EPAPmin: 4-15 cm H2O
- EPAPmax: 4-15 cm H2O
- PSmin: 0-6 cm H2O (default 3) – previously was 3-6
  - Default is 3, mainly for comfort, to assist with work of breathing
- PSmax: 5-20 cm H2O (PS min to IPAP 25)
- Max pressure: 25 cm H2O
- Rate: Auto (15)
  - 15 is default, but adjusts down as low as 10 if patient meeting minute ventilation requirements in last 4-6 breaths
- Ramp time: 0-45 min
- Can’t input Inspiratory time or Rise time
ASV Effectiveness

- Both Machines very effective in reducing AHI in CSA
ASV Indications – AASM Practice Parameters

- CSA in CHF
  - Initial treatment still optimization of medical therapy and CPAP
  - SERVE-HF Trial now shows some long term data
    - Increased risk CV death in *Chronic* Heart Failure (NYHA 2-4) AND EF <45% in Moderate to severe *CSA predominant* SDB (>50% of AHI is central apnea)
      - A post-hoc analysis seems to show worse ASV-associated risk as LVEF declines further below 45%
  - Previous studies with short term follow up showed some improved outcomes
    - Improved survival
    - Decreased AHI (31 lower) – 26 studies
    - Improved cardiac function (LVEF 5.5% higher) – 17 studies
    - Decreased cardiac death – 3 studies
    - Improved exercise tolerance & quality of life
- Increased cost
• Recommendation 1: Adaptive servo-ventilation (ASV) targeted to normalize the apnea-hypopnea index (AHI) should not be used for the treatment of CSAS related to CHF in adults with an ejection fraction ≤ 45% and moderate or severe CSA predominant, sleep-disordered breathing. (STANDARD AGAINST)

• Remarks: The recommendation against using ASV is based on evidence for increased risk of death in CHF patients with LVEF ≤ 45%.

• Recommendation 2: Adaptive servo-ventilation (ASV) targeted to normalize the apnea-hypopnea index (AHI) can be used for the treatment of CSAS related to CHF in adults with an ejection fraction > 45% or mild CHF-related CSAS. (OPTION)
ASV Indications (cont.)

- Insufficient evidence in opioid related SA, complex SA or primary CSA
  - Barely any outcomes studies for these
  - Studies on complex SA show good effectiveness of ASV
  - Mixed studies on effectiveness in opioid related CSA
    - Recent study showed good long term efficacy and compliance
      - Mean 25 month f/u, usage 5.1 hrs, AHI 3.3, ESS decrease by 2
    - Controversial to use in opioid CSA without hypoxemia or desats

CSA in Opioid Use - CAI

ASV Indications

- Do not use if hypoventilation
  - Targets patient’s own ventilation, which is inadequate in patients with hypoventilation
When To Switch To ASV

- Very severe central apnea on initial titration
  - To the point you feel may cause harm to patient if sent home on CPAP or BiPAP
  - If patient cannot tolerate CPAP or BiPAP
- If after 1-2 month follow up, high suspicion for persistent central sleep apnea
  - High AHI on download
  - Patient having persistent insomnia, arousals or daytime sleepiness, despite adequate compliance
CSA CMS Guidelines

- MUST be aware of this if switching patients to ASV in middle of study – must meet criteria
  - Need to calculate central AHI if possible
- Central AHI >5
  - Can be on titration if complex sleep apnea
- Central AHI >50% of total AHI
- Symptoms of excessive sleepiness or disrupted sleep
- CPAP has been ruled out as effective therapy
Transplant Free Survival in CHF Patients With CSA on CPAP

CPAP responders, n = 57
AHI at 3 months < 15/hr, mean = 6.5

Control, n = 110
AHI at 3 months ≥ 15/hr, mean = 36

CPAP non-responders, n = 43
AHI at 3 months ≥ 15/hr, mean = 35

*versus control: HR = 0.36, p = 0.040

Artz, Circ 2007 CANPAP
Effect of ASV on Survival in CHF

Data from Takama and Kurabayashi, Circulation J, 2012

- Good adherence group: 42% on β blocker, n=58
- Poor adherence group: 29% on β blocker, n=28

Log-rank test: p = 0.0046
Cox model: OR = 0.53, CI = 0.27, 0.99, p = 0.046
SERVE-HF Reasons for results?

- Increase in stress on heart?
- Bad data?
- Using older style ASV machine?
ResMed suggested algorithm

For patients with moderate to severe predominant central sleep apnea, use this flowchart to assess which patients should be considered for ASV therapy.²

First, determine if patient is at risk for heart failure (HF)

- Diagnosed with HF?
  - YES
  - NO
  - UNSURE
    - Recent measure of LVEF available?
      - YES
      - NO
      - UNSURE
  - Cardiovascular events or HF meds in medical history?
    - YES
    - NO
    - UNSURE

- Signs and symptoms of HF?
  - YES
  - NO
  - UNSURE
    - Cardiology check?
      - YES
      - NO
      - LVEF ≤ 45%?
        - YES
        - NO
        - ASV not indicated
      - NO

- ASV can be considered
### New York Heart Association (NYHA) Classification of Heart Failure

<table>
<thead>
<tr>
<th>Class</th>
<th>Patient Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I (Mild)</td>
<td>No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, rapid/irregular heartbeat (palpitation) or shortness of breath (dyspnea).</td>
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<tr>
<td>Class II (Mild)</td>
<td>Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, rapid/irregular heartbeat (palpitation) or shortness of breath (dyspnea).</td>
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<tr>
<td>Class III (Moderate)</td>
<td>Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, rapid/irregular heartbeat (palpitation) or shortness of breath (dyspnea).</td>
</tr>
<tr>
<td>Class IV (Severe)</td>
<td>Unable to carry out any physical activity without discomfort. Symptoms of fatigue, rapid/irregular heartbeat (palpitation) or shortness of breath (dyspnea) are present at rest. If any physical activity is undertaken, discomfort increases.</td>
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</tbody>
</table>
CSA in CHF – my thoughts

- Can be creative with CPAP
  - Use lower pressures to avoid inducing worse central apnea
  - Use POSITIONAL therapy
  - Use supplemental oxygen in combo with CPAP – if insurance can approve
  - Use CPAP in combination with sleep aid

- Consider not treated CSA – maybe just O2 alone for desats
  - ? Will insurance pay for O2 if not on PAP therapy if decision made not to treat the CSA with PAP???
Patient Example 1

• Had patient with CHF who did fair with an ASV titration (improved CSA somewhat, still persistnet cheyne-stokes, but sats better), but the patient felt MUCH better after study, EF borderline 3 years ago, family wants to take risk of ASV.
• What would you do?
• I repeated Echo, EF is now <30%
• Decided to do trial of CPAP with positional therapy and see if responds at home
Patient example 2

• Severe CHF, did not respond to CPAP very well
• Did CPAP with oxygen – saturations MUCH improved
• Patients son willing to pay for O2 out of pocket as did not meet requirements (sats not <89% for total of 5 minutes with CPAP)
Patient example 3

• Patient on ASV already, been doing well for years
• h/o severe CHF EF <25%
• Explained patient risks and turned his ASV machine to CPAP mode
• Patient trialed for 2 months, felt much worse on CPAP, decreased QOL
• Switched patient back to ASV as he was willing to take the risk
My Thoughts on ASV Titrations

• Usually we are titrating based on hypopneas
• Always watch for high leaks, very common! – adjust mask
• Flow limitation, paradoxical breathing, snoring: ↑ min EPAP
  • Keep an eye on what machine is automatically doing with EPAP and PS: watch the pressure line
• If none of above and breathing looks periodic, centrals occurring or PS maxing out: ↑ Max PS
• If still ambiguous hypopneas:
  • Try backup rate: May be helpful for opioid related CSA
  • Try increasing Min PS: can help with patient comfort, decrease arousals
  • Consider adding supplement O2 (especially if low sats)
• See how they look in the lateral position
• If arousals very frequent – try hypnotic
Watch for Breath Stacking

- Patient below had a sleeping baseline rate of 9-10 bpm
- Switched to a backup rate of 12 and started breath stacking
- Need to pick rate 1-2 below baseline rate.
ASV Titrations (cont.)

• If pressure intolerance – patient complains, frequent arousals:
  • Increase Min PS
  • Try adjusting rise time or Biflex (on Respironics)
  • Consider decrease Max PS (as long as central events controlled)
• O2 sats low despite events being controlled: ↑ Min PS, consider O2
  • Be careful: This may be a sign of hypoventilation or lung disease
  • If obstructive lung disease: backup rate with decreased I-time
  • If restrictive lung disease: backup rate with increased I-time
• If all else fails:
  • Consider switching brand of ASV machine or trying BiPAP ST
  • Consider CPAP at lower pressures with supplemental O2 +/- hypnotics
  • Consider AVAPS (if suspicion for hypoventilation or opioid induced)
    • AVAPS not effective for CSB or periodic breathing
Note position and sleep stage differences

Central Apneas
Obstructive Apneas
Hypopneas

ASV started
Min EPAP increased

PLM
SpO2

Time
Hrs Epoch
Obstructive apneas on baseline

Central apneas on CPAP (absent in REM)

Down titration of CPAP did not improve centrals
Obstructive & central apneas on CPAP

Central apneas on BiPAP

ASV started
With CPAP
With ASV
ASV Follow Up

• Goals:
  • improve arousals, daytime sleepiness
    • No good evidence on this
  • Improve Quality of life
  • ? Improve cardiac function & survival in CHF patients >45% EF

• Problems
  • Residual AHI
    • ? Obstructive vs Central
    • Frequent arousals/insomnia – try hypnotic
    • High leaks
  • Pressure intolerance - Try ramp, Biflex, adjust rise time, or decrease pressure
  • High leaks – mask adjustment, pressure decrease
  • Residual sleepiness – look for other causes
## Therapy Data Summary - All Data

### Compliance Summary

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<td>Days with Device Usage</td>
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<td>Percent Days with Device Usage</td>
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<td>Cumulative Usage</td>
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<td>Maximum Usage (1 Day)</td>
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<td>Average Usage (All Days)</td>
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<td>Average Usage (Days Used)</td>
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<td>Minimum Usage (1 Day)</td>
<td>2 hrs. 42 mins. 55 secs.</td>
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<td>Percent of Days with Usage &gt;= 4 Hours</td>
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<td>Percent of Days with Usage &lt; 4 Hours</td>
<td>36.8%</td>
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<td>Total Blower Time</td>
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### BiPAP autoSV Advanced Summary

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<td>Average Device EPAP Pressure &lt;= 90% of Time</td>
<td>11.9 cmH2O</td>
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<td>Average Percent of Night in Periodic Breathing</td>
<td>0.0%</td>
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<tr>
<td>Average Time in Large Leak Per Day</td>
<td>1 mins. 41 secs.</td>
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<tr>
<td>Average Breath Rate</td>
<td>12.1 bpm</td>
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<tr>
<td>Average Minute Vent</td>
<td>7.3</td>
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<td>Average AHI</td>
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### Settings

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<td>Max Pressure:</td>
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<td>Backup Rate:</td>
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<td>Flex Setting:</td>
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High Leak Causing Increase AHI

AHI better when leak better
Summary/Conclusions

• CSA is a prevalent disorder in certain populations
• Can lead to worse outcomes in CHF, but not much data on long term outcomes in other forms of CSA
• ASV often first line of treatment, improves outcomes in CHF
• Switch to ASV for severe centrals or poor clinical response to CPAP/BiPAP on follow up
• The 2 main ASV machines differ in mechanism, but both achieve good results
• ASV titration is SLOW
  • Always watch for leaks
  • Watch patient and machine closely to determine next step in titration
• Watch for residual symptoms or elevated AHI on follow up
Questions??
References

- ResMed ASV slides – including titration protocols
- Respironics ASV slides – including titration protocols
- Westhoff, et al. Sleep Breath On line 2/25/11
- Oldenburg et al. SLEEP 2012 Poster and Abstract.
- Javaheri, S. et. al, ERS 2009, Session #52