

Use of Adaptive Servo-ventilation (ASV) for People With Heart Failure and Trouble Sleeping

People with heart failure often have trouble breathing while asleep. Studies have shown that roughly 2 out of every 3 patients with heart failure will have some sort of breathing problem while asleep (known as sleep disordered breathing).



What is Sleep Disordered Breathing (SDB)?

SDB is a general term used to describe various different abnormalities in breathing pattern which occur during sleep, including obstructive and central sleep apnea. Obstructive sleep apnea (OSA) is a common disorder which affects roughly 10% of the US population and approximately 1/3 of people with congestive heart failure. OSA patients have reductions or stoppages in airflow despite ongoing respiratory efforts. In contrast, central sleep apnea (CSA) patients have reductions or stoppages in airflow without respiratory effort. Cheyne Stokes respirations (CSR) is a special form of CSA which is seen in roughly 1/3 people with congestive heart failure. OSA and CSA sometime occur in the same individuals either at different times of the night or from one night to the next. Thus, the term SDB is used to refer to both OSA and CSA together since the distinction is sometimes hard to make.

Is SDB bad for my health?

Most, but not all, studies suggest that heart failure patients with SDB have worse prognosis than matched heart failure patients without SDB. This means they can have more symptoms and poorer health and disease control. Patients with either OSA or CSA are thought to be at risk of increased mortality and risk of hospitalizations. There have been some theories suggesting that CSR may be beneficial for certain patients, but this view has not been widely accepted by experts.

What is the new medical research study called SERVE-HF all about?

Results of a new medical research study were reported at the recent American Thoracic Society medical conference in May 2015 in Denver CO. The study involved over 1300 patients with CHF and CSA along with a specific type of heart problem (impaired left ventricular systolic function, ejection fraction $\leq 45\%$). The results led to a field safety notice which had some concerning findings. The study was a randomized trial which was sponsored by the company ResMed comparing adaptive servo-ventilation (ASV) with usual medical

therapy. The primary outcome was a composite measure of either mortality or unplanned hospitalization which showed no difference between groups. Of note, sudden cardiac death was more common in the ASV group as compared to the medical therapy group (10% vs. 7.5%, $p < 0.05$); this difference was considered to be not likely due to chance alone. Experts are currently not clear why this risk occurred. Based on this finding, patients who are using ASV are advised to talk with their health care provider about stopping it.

Should I stop my ASV?

It depends, talk to your health care provider. Many patients have received ASV for other reasons that were not studied in the SERVE-HF study. For example, ASV has been used for complex sleep apnea (treatment emergent central apnea), narcotic induced central apnea, SDB in people with CHF with preserved ejection fraction. There is no good reason at this time to stop using ASV for these conditions. For patients who have a new diagnosis of CSA with impaired left ventricular systolic function, we would not recommend starting ASV at this time. For patients with CSA and CHF with reduced ejection fraction, we believe the decision needs to be individualized in communication with your specialist. Some patients feel much better on ASV and are willing to take a small potential risk of sudden cardiovascular death because of their improved quality of life from ASV. Some patients who are struggling with ASV may be very willing to give it up, since they may not be using it very much in the first place. For patients who are on ASV with CHF, a careful medical evaluation would be worthwhile. Optimization of medical therapy would be beneficial since withdrawing ASV abruptly may also have risks, particularly in patients whose condition is not controlled optimally. In some cases, transitioning patients from ASV to standard CPAP could also be considered. For example, patients who have never been on CPAP who have OSA may not need ASV and in such cases transitioning to CPAP would seem reasonable. In patients who have previously failed CPAP, ASV withdrawal could be considered,

although the optimal management of these patients remains unclear. Treatment options such as oxygen and medicines that help the body clear extra fluids, such as acetazolamide, could be alternatives you can discuss with your health care provider. Careful monitoring of electrolytes, such as potassium and magnesium levels, would also seem reasonable. Talk to your specialist before you decide what to do.

Why is ASV a problem?

The findings of this new study were unexpected and thus experts have been discussing why this finding might have happened.

1. The possibility exists that the findings were by chance (bad luck) and that more studies will be needed before we can believe that ASV is really harmful. Sometimes imbalances occur at randomization such that one group is sicker than the other by chance and thus the poor outcomes may relate to patient characteristics rather than a real effect of the ASV therapy.
2. There may be direct effects of ASV which could affect breathing pattern or heart function, although standard CPAP has similar effects and is not thought to carry the same risks. The ASV settings can sometimes lead to hyperventilation (breathing too much) which can lead to respiratory alkalosis (low carbon dioxide, high pH in the body) and could have associated electrolyte abnormalities (such as potassium level). These metabolic changes, if present, could trigger *arrhythmias* which can lead to sudden cardiac death.
3. Another possibility is indirect effects of ASV. For example, changes in medications or health behaviors can occur in any *un-blinded* study which can be important. For example, if patients stop taking their medications, or start excessive daily activities abruptly, or the doctor changes their medications, these effects could be problematic at least for some patients.

Because the details are unclear, we do not know exactly why cardiac sudden death occurred in some patients on ASV therapy. We have speculated here, but await further data.

What if I have a different brand of ASV machine?

Several companies make ASV machines including ResMed, Philips Respironics etc. The SERVE-HF study involved the ResMed ASV machine (adaptive servo-ventilation). Philips Respironics released a statement suggesting their device (auto servo-ventilation) is likely to have similar effects to that of ResMed given that the algorithms are similar. Thus, the type of device probably does not make a major difference from the standpoint of what is recommended.

I have heart failure and don't feel great—should I see a sleep or lung specialist at this point?

Yes, the new findings suggest we need to be cautious about treating CSR, but there are still many contributors to sleepiness and fatigue that are common in heart failure which your health care provider can address. For example, insomnia, leg move-

ments, obstructive sleep apnea, and other factors may contribute to feeling poorly and should still be identified and treated.

I am on PAP (CPAP or APAP) but don't have heart failure, am I OK?

The new findings relate only to patients with congestive heart failure with impaired left ventricular function. Obstructive sleep apnea remains an important disease with important effects on health. You should continue CPAP therapy as it should make you feel better and may protect your heart. APAP (auto-titration PAP) is not related to ASV and thus there is no cause for concern based on the new findings.

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Glossary of Terms

Congestive Heart Failure—a build-up of fluid in the body due to the heart not working well

Respiratory effort—taking a breath; breathing

Ejection fraction—measure of how well the heart pumps blood

Randomized trial—type of research study in which patients are randomly assigned to one treatment or another

Un-blinded study—type of research study in which both the patients and researchers know which treatment they are receiving

Field safety notice—medical care notice sent out to health care providers and institutions about a safety issue

Primary outcome—the main outcome of a research study

Composite measure—an outcome of a research study that combines two or more measurements

Optimized medical therapy—using the best available medicine(s) or other treatment to help a person manage a health problem/disease

Arrhythmias—abnormal heart rhythm

Sudden cardiac death—unexpected death due to heart problems

Additional Resources:

American Thoracic Society

www.thoracic.org/patients

American Heart Association

<http://www.heart.org/HEARTORG/Conditions>

American Academy of Sleep Medicine

<http://www.sleepeducation.com/>

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