

March 20, 2017



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Research on Treating Sleep Apnea with Adaptive Servo-ventilation Published in the Journal of the American College of Cardiology (JACC)

ResMed's CAT-HF study identifies potential treatment for heart failure patients with preserved ejection fraction and sleep apnea

SAN DIEGO, March 20, 2017 /PRNewswire/ -- ResMed (NYSE:RMD) today announced publication of a study in the *Journal of the American College of Cardiology* (JACC), which investigated whether treatment of moderate to severe sleep-disordered breathing (obstructive or central sleep apnea) with adaptive servo-ventilation (ASV) therapy could improve cardiovascular outcomes in patients who were hospitalized for a sudden worsening of their heart failure (acute decompensated heart failure) over six months.*

"Cardiovascular Outcomes With Minute Ventilation-Targeted Adaptive Servo-Ventilation Therapy in Heart Failure – The CAT-HF Trial" is a multicenter, randomized, controlled Phase II trial funded by ResMed to broaden the understanding of how best to treat diagnosed sleep apnea in patients that also have a particular form of heart failure.

The overall study results were neutral (Wilcoxon p-value = 0.717). However, the study revealed a pre-specified subgroup analysis that showed a statistically significant improvement in the primary endpoint for people with moderate to severe sleep-disordered breathing and heart failure with preserved ejection fraction (HFpEF) (Cox p-value = 0.036). The primary endpoint was cardiovascular outcomes measured as a Global Rank Score that included survival free from cardiovascular hospitalization and change in functional capacity as measured by the six-minute walk distance. The study also assessed changes in functional parameters, arrhythmias, biomarkers, quality of life (QoL), and sleep and breathing.

Leading cardiologists say the improvement for HFpEF patients with sleep apnea signals a potential breakthrough in treatment options for those patients, and call for more research to be done.

"There are no level of evidence 1A guideline recommended therapies specific for HFpEF patients, which accounts for half of all people living with chronic heart failure," said Christopher M. O'Connor, MD, the study's lead investigator, cardiologist and CEO of the Inova Heart and Vascular Institute. "These results from CAT-HF suggest we need to further study the role of whether addressing sleep-disordered breathing can help people who have

heart failure with preserved ejection fraction."

"This is another great step forward in understanding the connection between sleep-disordered breathing, heart failure and proper treatment methods," said Dr. Tony DeMaria, a cardiologist from the University of California – San Diego. "We are looking forward to what future heart failure research can tell us about key links to other conditions our patients face."

"Having JACC publish this research is incredibly positive, encouraging others to look deeper into the potential benefits of ASV therapy," said Dr. Carlos Nunez, ResMed Chief Medical Officer. "I hope future studies can further establish these benefits and lead to life-improving treatment recommendations for countless patients with sleep apnea."

About sleep-disordered breathing

Sleep-disordered breathing encompasses a spectrum of breathing problems during sleep. The two most common types of sleep apnea, a condition that results in repetitive pauses in breathing during sleep, are obstructive sleep apnea and central sleep apnea.

Obstructive sleep apnea is a sleep disorder in which the throat muscles relax, block the airways and stop the flow of breath during sleep. Central sleep apnea is a sleep disorder in which the brain does not transmit the "breathe" signal to the muscles that control breathing during sleep. In either situation, the lack of oxygen causes the person to wake up to catch their breath and start breathing again, interrupting continuous sleep. This may occur multiple times in an hour.

About chronic heart failure

Chronic heart failure occurs when the heart does not pump enough blood to meet the needs of the body. When the heart contracts normally but does not relax sufficiently to fill the chamber with enough blood, it is classified as heart failure with preserved ejection fraction. If the heart cannot contract to pump enough blood, it is heart failure with reduced ejection fraction.**

An estimated 26 million people worldwide have heart failure,¹ split roughly half-and-half between those with preserved vs. reduced ejection fraction.² It is believed that sleep-disordered breathing may be found in 69 percent of patients with heart failure with preserved ejection fraction (HFpEF),³ far more commonly than in the general population. People with heart failure often report poor sleep as a symptom.

About the CAT-HF study

The paper was based on the CAT-HF trial, first presented at the European Heart Failure conference in Italy in 2016. CAT-HF was designed to address whether cardiovascular outcomes could be improved with adaptive servo-ventilation (ASV) therapy for either obstructive or central sleep apnea after hospitalization for sudden worsening symptoms for people with both preserved and reduced heart failure.

CAT-HF is a randomized controlled trial that evaluated whether adding ASV to optimized medical therapy could improve cardiovascular outcomes at six months for people with acute decompensated heart failure (HF) patients compared to optimized medical therapy alone.* Patients were enrolled with a prior or new diagnosis of heart failure after admission to the hospital with sudden worsening of heart failure symptoms.

About ResMed

ResMed (NYSE:RMD) changes lives with award-winning medical devices and cutting-edge cloud-based software applications that better diagnose, treat and manage sleep apnea, chronic obstructive pulmonary disease (COPD) and other chronic diseases. ResMed is a global leader in connected care, with more than 2 million patients remotely monitored every day. Our 5,000-strong team is committed to creating the world's best tech-driven medical device company – improving quality of life, reducing the impact of chronic disease, and saving healthcare costs in more than 100 countries.

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* The AirCurve 10 ASV device is indicated for the treatment of patients weighing more than 66 lb (30kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing.

** ASV therapy is contraindicated in patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF $\leq 45\%$) and moderate to severe predominant central sleep apnea. All patients diagnosed with sleep apnea should consult with their physician to determine the most appropriate treatment for their sleep apnea.

1 Ambrosy PA et al. *JACC* 2014

2 Givertz MM et al. *Am J Cardiol* 2001

3 Bitter T et al. *Eur J Heart Fail* 2009

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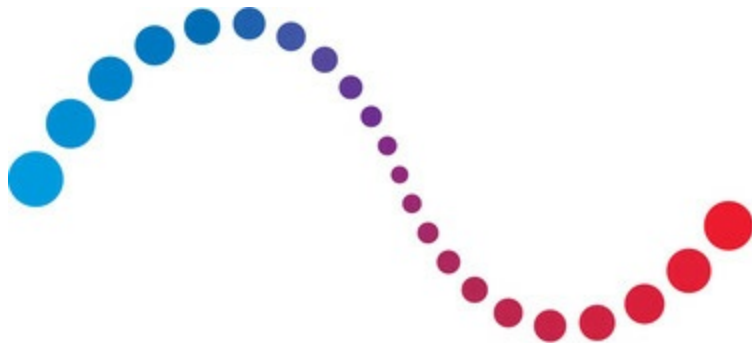
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