

ESC Congress 2014 Highlights: Heart Failure Patients with Sleep-Disordered Breathing More Accurately Diagnosed Through At-Home, Contactless SleepMinderTM Device Than Single Hospital-Based Assessment

Study highlights bedside device could reduce misdiagnosis of sleep-disordered breathing common heart failure co-morbidity, support optimal treatment and reduce need for inpatient care

BARCELONA, Spain--(BUSINESS WIRE)-- ResMed (NYSE: RMD), a pioneer and global leader in sleep and respiratory medicine, today announced results from a study presented at the ESC Congress 2014 in Barcelona, Spain, looking at the use of the at-home, contactless, bedside SleepMinder™ device to diagnose sleep-disordered breathing (SDB), the most common co-morbidity in patients with heart failure (HF).^{1,2} The study also assessed how SleepMinder™, when used over two weeks, compared to a current gold-standard of diagnosis, a single night assessment via inpatient polysomnography (PSG). The investigating team reported that, after using SleepMinder™ for two weeks, 57% of patients were consistently above a threshold that would require treatment for their SDB (AHI≥15). This rose to 74% in patients who were followed up for 12 months.¹

"Sleep disordered breathing is the most common heart failure co-morbidity, yet the diagnosis is often missed," said Professor Martin Cowie, Professor of Cardiology, Royal Brompton Hospital, London, UK and co-author of the study. "This condition affects millions of heart failure patients across Europe and can lead to significantly worse outcomes if not correctly diagnosed and treated. This study showed that, by using a device that can gather longer-term data, we can offer a means of diagnosis that is both practical for patients, doctors and health services and may well be more accurate than existing techniques that require inpatient care. It is vital that cardiologists explore how they can help to establish more routine use of this technology in the heart failure patient pathway."

SDB is typically diagnosed in patients with HF by calculating the Apnoea-Hypopnea Index (AHI), typically from a single overnight PSG study conducted in a hospital or specialist sleep centre. However, HF patients commonly experience volume load changes that can make AHI highly variable in this population over time. Mean AHI assessment, over a longer period

is therefore likely to be more accurate. SleepMinder is a non-contact, bedside, nocturnal respiratory monitor that can be placed next to a patient's bed to collect data on SDB over longer periods. Two weeks represent a useful period for SDB assessment to be gathered. This study involved 39 adult patients with HF who were assessed over 12 months. Following two weeks of assessment, mean AHI was consistently above the treatment threshold for 57% of patients. This rose to 74% after 12 months of follow up. 1

These results can have significant implications for the routine diagnosis of this prevalent condition in HF.

Sleep disordered breathing in heart failure

SDB is the most common co-morbidity in HF, affecting between 50-75% of the 15 million HF patients in Europe. ^{3,4,5} However, it remains underdiagnosed and one of the least recognised co-morbidities by cardiologists, despite being linked to worse outcomes including mortality, hospitalisations and quality of life. ⁶

Sleep disordered breathing at the ESC Congress 2014: Highlighting the importance of correct diagnosis and treatment in cardiac patients

"Benefit of positive airway pressure (PAP) therapy in patients with sleep apnoea (SA) in Germany: a retrospective comparative cohort analysis based on a statutory health insurance (SHI) database"

In an additional study, presented at a Rapid Fire session, data were presented highlighting that treating cardiac patients with SDB with positive airway pressure (PAP) device therapy could reduce three year mortality by up to 38%. In patients with coronary heart disease (CHD) or HF, three-year mortality was reduced by 37.9% (4.5% vs 7.2%, p=0.0002) and 31.6% (14.7% vs 21.4%; p<0.0001) respectively, highlighting the importance of correct diagnosis and treatment of this prevalent co-morbidity.

The analysis assessed outcomes for a total of >4 million individuals covered by the German Statutory Health Insurance (SHI) database (approximately 5% of the German SHI population). PAP therapy was initiated in 4,068 patients with sleep apnoea. Propensity score was used to define a control group of equal number who received usual care (no PAP).⁷

ResMed in Cardiology: SERVE-HF, the largest randomised trial of sleep-disordered breathing in heart failure

A common type of SDB, CSA-CSR, can be successfully treated with PaceWaveTM Adaptive Servo-Ventilation (ASV) therapy. In 2013 ResMed completed enrolment of the 1,325th patient in SERVE-HF, the world's largest randomised study investigating by what degree the treatment of central SDB (central sleep apnoea) with PaceWaveTM ASV may improve survival and outcomes of patients with stable HF. Results are expected to report in 2015 and could lead to significant changes in cardiology clinical practice.

Study information, updates, and news can be obtained at the dedicated SERVE-HF study website www.servehf.com

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NOTES TO EDITORS

About ResMed

ResMed is a leading developer, manufacturer and distributor of medical equipment for treating, diagnosing and managing SDB and other respiratory disorders. We are dedicated to developing innovative products to improve the lives of those who suffer from these conditions and to increasing awareness among patients and healthcare professionals of the potentially serious health consequences of untreated SDB. For more information on ResMed, visit www.resmed.com.

References

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- ⁷ H. Woehrle et al. Benefit of positive airway pressure (PAP) therapy in patients with sleep apnoea (SA) in Germany: a retrospective comparative cohort analysis based on a statutory health insurance (SHI) database. ESC Congress 2014, abstract 90918 presented as part of the Rapid Fire session on 31 August 2014.

Photos/Multimedia Gallery Available: http://www.businesswire.com/multimedia/home/20140831005009/en/

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