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**FOR RELEASE**

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Session: D98 After Serve-HF: Now What?

Wednesday, May 18, 2016, 1:30–1:45 p.m.

Location: Room 2001/2003 (West Building, Level 2), MOSCONE CENTER

**Heart Failure Patients With Predominant Central Sleep Apnea at Higher Risk for Serious Complications Than Those Who Also Have Obstructive Sleep Apnea**

ATS 2016, SAN FRANCISCO — Chronic heart failure (CHF) patients with predominant central sleep apnea (CSA) are at higher risk for death and unplanned hospitalization than those who have both CSA and obstructive sleep apnea (OSA), whether or not they receive adaptive servo-ventilation (ASV) therapy. These interim results from the ongoing FACE Multicentre National Cohort Study, a French prospective observational study, were presented at the ATS 2016 International Conference.

“Our results illustrate what is happening in real life for these patients, and highlight how CHF patients can exhibit a variety of traits, both in terms of respiratory and cardiovascular disease classification,” said lead author Renaud Tamisier, MD, PhD, from Grenoble Alpes University, France. “This will be crucial in determining who will benefit most from CSA treatment.”

Central sleep apnea affects about 10-20% of people with sleep apnea, and is far less common than obstructive sleep apnea, which CSA patients may also have. However, CSA affects 30% of CHF patients and results in breathing instability during sleep, alternating between hyperventilation and hypoventilation, the former caused by a hypersensitivity to carbon dioxide and the latter causing apnea. This is far different from OSA, which is caused by partial or complete blockage of the throat. Adaptive servo-ventilation is a type of advanced positive airway pressure technology that has been shown more effective at treating CSA than CPAP and improves heart function in CHF. Chronic heart failure is a disorder in which the heart does not properly pump blood.

The ongoing FACE study involves 301 stable CHF patients with preserved ejection fraction and with low ejection fraction, of whom 80% have New York Heart Association functional class II/III heart failure, a classification system that categorizes the severity of CHF on a scale of one

to four. For this leg of the study, researchers looked at morbidity and mortality, changes in cardiac function, respiratory/sleep data, whether they had reduced or preserved left ventricular ejection fraction (LVEF), predominant CSA or co-existing CSA-OSA, and compliance with ASV therapy.

Predominant CSA and co-existing CSA were present in 70% and 30%, respectively, of study participants and 75% of patients had severe sleep apnea. Seventy-four percent of participants agreed to have ASV therapy.

Although predominant CSA patients and CSA-OSA patients had similar heart disease severity, patients who had predominant CSA and were in the most severe NYHA class had higher all-cause mortality rates and more unplanned hospitalizations. This held true whether or not they complied with ASV therapy.

"We already know that CHF patients with CSA have a poor prognosis," said Dr. Tamié. "However, the significance of this remains a question. Is this related to CHF status, or does CSA have an inherent pathogenesis that worsens the evolution of CHF? We hope to answer these questions."

Dr. Tamié added, "CHF patients in the most severe NYHA class did not differ in terms of prognosis, whether they were on ASV therapy or not. This is close to what the SERVE-HF trial concluded. Patients with the most severe CHF do not seem to benefit from treating their CSA with ASV. Questions remain about the value of alternative treatments."

The FACE study will provide data on CHF patients eligible for ASV, with patients followed for two years. Twenty-two research centers are participating. Data collection is expected to be complete by the end of 2019.

SERVE-HF was a multicenter randomized trial that collected data on the effect of treatment with ASV in patients with low ejection fraction heart failure and predominant CSA or Cheyne-Stokes respiration, a syndrome that is often associated with CSA.

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Abstract 6864

Morbidity and Mortality of Chronic Heart Failure (CHF) Patients Treated by Adaptive Servo-Ventilation (ASV): Interim Data of the FACE Multicentre National Cohort Study

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Scientific Abstract

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29 - Sleep Disordered Breathing/Adult/Cardiovascular Outcomes/Sleep and Respiratory Neurobiology (SRN)

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## Abstract Body

**Rationale:** Central Sleep Apnea (CSA) associated or not with coexisting Obstructive Sleep Apnea (CSA-OSA) is common in CHF patients and is associated with a worse prognosis. ASV therapy has proven effective in all-type sleep apnea resolution. The FACE multicentre national observational cohort study is investigating the long-term use of ASV over 2 years' follow-up in CHF patients eligible for ASV, to provide additional data in routine clinical practice and complementary information to SERVE-HF trial. Interim data are presented.

**Methods:** Morbidity and mortality data, changes in cardiac function, respiratory/sleep data, quality of life (Minnesota Living with Heart Failure questionnaire) were assessed in stable CHF patients with reduced or preserved Left Ventricular Ejection Fraction (LVEF) and CSA±OSA, compliant or not with ASV therapy (ResMed, AutoSet CS).

**Results:** Interim analysis was performed in 301 CHF patients in whom 87% were in NYHA functional class II/III, mainly ischaemic aetiology (53%). Baseline characteristics were: age  $70.1 \pm 10.9$  y, 87% male, body mass index  $27.9 \pm 4.9$  kg/m<sup>2</sup>. ESS score was  $7.5 \pm 5.0$  (75% had no severe sleepiness). Major comorbidities were hypertension (72%), dyslipidaemia (60%), atrial fibrillation (44%), diabetes (39%) or cerebrovascular event (29%). Drug treatment included  $\beta$ -blockers (72%), ACE inhibitors (56%), diuretics (72%), angiotensin II receptor blockers (24%) and aldosterone antagonists (28%); non-drug therapy was a cardiac resynchronization device (12%) or implantable cardioverter defibrillator (17%). LVEF was reduced (REF) or preserved (PEF) in 68% and 32% of pts, respectively. Mean apnoea-hypopnoea index (AHI) was  $42 \pm 17/h$  and 75% of patients had severe sleep apnoea (AHI > 30/h). Predominant CSA and coexisting CSA-OSA were present in 70% and 30%, respectively. Compared to CHF-REF, CHF-PEF patients were older, more obese, and had fewer CHF-complaints related, more frequent COPD and more severe CSA. 74% of patients agreed to receive ASV therapy. Patients declining ASV therapy were more often female with lower BMI and AHI. Although predominant CSA and CSA-OSA patients exhibited similar cardiac disease severity and medical treatments, all-cause mortality and unplanned hospitalization at 3 month-FU were significantly increased in CHF patients with predominant CSA (HR=3.0, p=0.04) and the most severe NYHA class (HR=2.5, p=0.03) irrespective of ASV therapy compliance.

**Conclusion:** CHF patients with coexisting CSA-OSA may have a different prognosis under ASV therapy compared to CHF with predominant CSA. FACE cohort study turns out to be a very useful clinical investigative tool in the understanding of the impact of ASV treatment in CHF patients with CSA. Longer follow-up is expected.

