Treatment of Sleep-Disordered Breathing with Predominant Central Sleep Apnoea by Adaptive Servo-Ventilation in Patients with Heart Failure (SERVE-HF)


Sleep disordered breathing (SDB) is very common in chronic heart failure (HF):
- 76% have SDB; 40% with central sleep apnea/Cheyne-Stokes respiration (CSA/CSR) and 36% with obstructive sleep apnea (OSA)\(^1\)
- 51% have moderate/severe SDB (AHI ≥ 15)\(^1\)

Chronic HF patients with CSA tend to have a higher NYHA class, a higher frequency of nocturia, much lower systolic blood pressure, and a higher prevalence of atrial fibrillation than do chronic HF patients with OSA.\(^1\)

Meta-analysis reported significant improvement in LVEF and good control of SDB in patients with CSA/CSR treated with minute ventilation-targeted adaptive servo-ventilation (MV-ASV).\(^2\)

SERVE-HF is the first study of adequate size and duration to determine whether treatment of CSA/CSR with MV-ASV can reduce morbidity and mortality in patients with chronic HF.

Primary Objective
- Evaluate the long-term effects and cost-effectiveness of MV-ASV on the morbidity and mortality of patients with stable HF due to left ventricular systolic dysfunction, already receiving optimal medical therapy (OMT), who have predominantly CSA/CSR.
- Primary study endpoint is time to first event:
  - All cause mortality or unplanned hospitalization for worsening HF
  - Cardiovascular mortality or unplanned hospitalization for worsening HF
  - All cause mortality or all cause unplanned hospitalization

Study Design
- Randomized, multi-center, controlled, parallel group design
- 1,325 subjects were randomly assigned to either active treatment (MV-ASV plus OMT) or control (OMT) in a 1:1 ratio.
- The trial is based on an event-driven design: the final analysis will be performed when 651 events have been observed or the study is terminated at one of the interim analyses.
- Subjects are to stay in the trial up to study termination; expected minimum 2 years.

Substudy
- Randomized, multi-center, controlled, parallel group design, performed within the SERVE-HF study
- 312 subjects were randomly assigned to either active treatment (MV-ASV plus OMT) or control (OMT) in a 1:1 ratio.
- Assess change in LVEF from baseline to 12 mo. as measured by Echo.

Study Status
- Active, follow up phase
- Subjects enrolled: 1,325
- First subject enrolled: February 2008
- clinicaltrials.gov reference: NCT00733343

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References