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- A Multi-center, Non-significant Risk IDE Study to be Conducted in the US
- Details for Study to date:
  - ~ 40 centers
  - N = 700 patients
- Primary Objectives:
  - Compare decompensation with device-based data
  - Develop and prospectively test algorithms
  - Develop future alert notifications
  - Develop future algorithms

Automated HF Decompensation Detection: Results from the Decompensation Detection Study (DECODE)

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The DECODE study collected CRT-D device-based data, patient weights and symptoms via a remote monitoring system (LATITUDE) in order to develop and evaluate automated methods to detect worsening heart failure decompensation events (HFE) defined as admission (or IV therapy) for heart failure. Methods: Patients (699) with CRT-D RENEWAL_ devices in VDD or DDD pacing modes were enrolled and followed for up to 2 years. Device-data, weights, and responses to symptom questions were available via remote monitoring. Phone follow-up every 3 months was used to screen for potential HFE. When HFE were confirmed, that patient and another randomly selected patient from the same center were entered into a detailed following with detailed examination of all medical records to confirm all HFE and HFE-free periods. These patients were randomly assigned to a development or evaluation set and patients and clinicians were blind to the assignment. The evaluation set was sequestered. Results: Detailed following patients were followed for 14.4 6 4.5 months (development n586) and 15.1 6 5.0 months (evaluation, n5115, p50.29).

Age, sex, HF status, etiology, pharmacological therapy, or co-morbidities were not different between sets. The development set was analyzed and a probability model to detect heart failure events up to 28-days in advance was developed using weight, symptoms, right atrial and shock lead impedance and HRV values. In development, the model demonstrated 48% sensitivity for early detection of documented HFE with 2 false-alerts per patient-year. When applied to the evaluation set, sensitivity dropped to 35%. Sensitivity for the pooled datasets was nearly 40%. Data items used by the model were selected due to high predictive content in the development set. However, predictive content was lower in the evaluation set (significantly for some) despite the random set assignments. Redeveloping the model on all data using refined data items improved sensitivity to 42%. Conclusions: In this study, device/sensor data typically changed prior to HFE and could be used to detect impending HFE events but performance was modest. This suggests that further investigation and/or additional sensors that are more closely related to HFE are required for clinically useful automated detection of HFE. These findings do support the hypothesis that it is possible to use device/ sensor data to predict heart failure decompensation.