HEART FAILURE MONITORING USING A MINIMALLY INVASIVE SUBCUTANEOUS INSERTABLE CARDIAC MONITOR: DEVELOPMENT AND VALIDATION OF AN INTEGRATED DIAGNOSTIC RISK SCORE

Rami Kahwash,[1], Javed Butler,[2], Shantanu Sarkar,[3], Jodi Koehler,[3], Michael Zile,[4]

[1]The Ohio State University; The Ohio State University, [2] Baylor Scott and White Research Institute, [3] Medtronic, [4] Medical University of South Carolina

Background:

Ambulatory management of heart failure (HF) patients require the ability to identify when patients are at highest risk of impending HF events (HFE). Subcutaneous insertable cardiac monitors (ICM) have investigational sensors to measure HF related diagnostics. With the advantages of minimally invasive procedure, remote monitoring capabilities not requiring daily patient compliance and providing a comprehensive set of cardiac diagnostic parameters, an ICM based HF monitoring system can potentially serve to bridge the gap between weight scales and pulmonary artery pressure monitoring.

Objectives:

The purpose of this study was to examine the performance of a multi-parameter dynamic HF risk score (HFRS) in class II/III HF patients with reduced and preserved ejection fraction using diagnostics measured by an ICM.

Methods:

Patients with history of HFE were implanted with an ICM equipped with investigational components to measure diagnostic parameters in a blinded fashion in the LINQ-HF and ALLEVIATE-HF phase-1 observational cohort. The ICM-HFRS was designed using a development dataset from part of the LINQ-HF study and validated with the remaining patients from LINQ-HF study and data from the ALLEVIATE-HF study. ICM-HFRS combined subcutaneous impedance derived fluid index, respiratory rate (RR), heart rate (HR), HR variability, atrial fibrillation (AF) burden, ventricular rate during AF, and activity duration into a single risk score which identifies the probability of HFE within 30 days. A high-risk alert threshold was derived from the development dataset. Sensitivity and unexplained detection rate of the high-risk alert were evaluated. Sensitivity was defined as the proportion of HFE where the ICM-HFRS was above the high-risk threshold in the 30 days prior to the HFE. Unexplained detection was defined as a high-risk threshold crossing (TC) event which was not accompanied by a HFE during and 30 days following end of TC event. HFEs were defined as

inpatient stay with a primary diagnosis of HF, or an observation unit or emergency room visit with IV diuresis administration.

Results:

The development dataset had 43 patients (65 ±10 years old, 65% male, 69% with LVEF ≥ 40%, 100% class-III); 42 patients and a total of 19 HFE included for data analysis. The validation dataset had 102 patients (68 ±11 years old, 63% male, 74% with LVEF ≥ 40%, 80% Class-III and 20% class-II); 94 patients with 19 HFE were included for data analysis. At the chosen high-risk threshold of 7.5%, the sensitivity was 73.7% with an unexplained detection alert rate of 1.38 per patient-year of monitoring in the development set with a median 47 days of early warning prior to HFE. In the validation dataset, 68% of the HFEs were preceded by the high-risk alert with a median early warning of 64 days and an unexplained alert rate of 1.5 per patient-year of monitoring.

Conclusion:

The ICM-HFRS provides a minimally invasive multi-parameter integrated diagnostic method with the ability to identify when patients are at increased risk of heart failure events. Whether interventions based on the ICM-HFRS would improve patient outcomes is currently being investigated in the ALLEVIATE- HF trial.