Evaluation of SharpSense algorithm enhancements in patients with heart failure

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**Introduction:** RHYTHM-HF study is a prospective, observational, multi-center cohort study, investigating the role of arrhythmias in the rehospitalization and death of patients with heart failure (HF). In all patients, continuous surveillance of arrhythmias is achieved via the implantation of an Abbott Confirm Rx injectable cardiac monitor (ICM) system. In this analysis, we retrospectively evaluated the effectiveness of recent algorithm enhancements (SharpSense™ Technology) using arrhythmic episodes detected by Confirm Rx ICM devices in this patient cohort.

**Methods:** We analyzed data from the first 196 subjects with Confirm Rx devices in the RHYTHM-HF study who had a successful transmission to Merlin.net. Pause, bradycardia, and atrial fibrillation (AF) episodes triggered by conventional sensing algorithms and transmitted between August 2017 and May 2019 were further analyzed using SharpSense™ technology. SharpSense™ utilizes arrhythmia adjudication parameters additional to conventional sensing algorithms. For pause and bradycardia episodes, the SharpSense™ algorithm adjudicates the episode as false positive if undersensing of R waves contributed to the trigger. For AF, SharpSense™adjudicates the episode as false positive if p waves are detected. Human adjudication combined with supervised adjudication using a machine learning model was used as the reference for assessing the performance of these enhanced algorithms.

**Result:** A total of 313,051 episodes from 196 devices were analyzed (pause: 164,227 [52%], brady: 108,100 [35%] and AF: 40,724 [13%]). The follow-up duration was 258 ± 159 days. SharpSense™ algorithm enhancements reduced false pause, bradycardia, and AF episodes by 98.5%, 96.1%, and 30.4%, respectively, with 0.7%, 0.5%, and 2.0% reduction in true episodes, respectively. There was a 97.9% reduction in total false positive episodes using SharpSense™; while 99.5% of true positive episodes were preserved. The number of detected pause, bradycardia, and AF episodes that remained after utilizing SharpSense™ technology was 116,691 (63% reduction in EGM review burden).

**Conclusion:** Confirm Rx with SharpSense™ technology significantly reduced false positive detections of pause, bradycardia, and AF episodes while maintaining high sensitivity. This may reduce the requirement for human review of arrhythmic episodes by healthcare professionals and thus improve clinic workflow.