Retrospective Analysis of Confirm Rx™ SharpSense™ Technology using Real-World Data from the SMART Registry

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Introduction: Recent enhancements in arrhythmia detection algorithms (SharpSense™ Technology) in Abbott Confirm Rx™ insertable cardiac monitor (ICM) aimed to improve the positive predictive value for detection of pause (absence of ventricular contraction), bradycardia (brady), and atrial fibrillation (AF) episodes while maintaining high sensitivity. In this study, we sought to characterize the clinical performance and clinical impact of the newly developed SharpSense™ Technology using data from the Confirm Rx SMART Registry, an ongoing registry that aims to collect real-world safety and performance data of the Confirm Rx ICM.

Methods: Episodes triggered by the Confirm Rx ICM without SharpSense technology from SMART registry patients were extracted from the Merlin.net patient care network and in-clinic device session records from April 24, 2018 through May 17, 2019. Pause, brady, and AF episodes were evaluated by the rhythm discriminators in SharpSense technology. These discriminators analyze ICM electrograms and reject original detections if undersensing of R waves (for brady and pause) or the consistent presence of p waves (for AF) is found. Human adjudication combined with supervised adjudication using a machine learning model was used as the reference to evaluate the performance of SharpSense discriminators.

Result: A total of 76403 episodes from 356 devices from 33 clinics were analyzed (pause: 44987 [59%], brady: 21005 [27%] and AF: 10411 [14%]). Devices were implanted in subjects with 56.9% (205/360) indicated for syncope, 35.0% (126/360) indicated for AF (previously diagnosed or suspected), 23.9% at risk for cardiac arrhythmias, and the rest for other reasons (palpitations, dizziness, cryptogenic stroke, etc.). The average duration of device implant to-date was 3.8 ± 2.5 months. SharpSense technology reduced false pause, brady, and AF episodes by 98.6%, 98.8%, and 42.4%, respectively, with 0.8%, 2.1%, and 4.7% reduction in true episodes, respectively. The overall false positive episode reduction with SharpSense Technology was 97.9% while overall relative sensitivity remained high at 97.9%. The total number of detected episodes after SharpSense technology was 21301, which represents a 78% reduction in EGM review burden.

Conclusion: This analysis demonstrated that the enhanced arrhythmia detection algorithms in SharpSense™ technology significantly decreases incidences of false pathological pause, bradycardia, and
AF episodes while maintaining high sensitivity, leading to significant efficiency in clinic review of transmitted episodes by Confirm Rx™ ICM. Further prospective analyses of SharpSense technology are needed to confirm these findings and are ongoing.