The Confirm Rx™ SMART Registry: Early Safety and Clinical Outcomes

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Introduction: Insertable cardiac monitors (ICM) are used to evaluate patients with unexplained symptoms such as palpitations and syncope resulting from underlying cardiac arrhythmias. It may also be implanted in patients with previously diagnosed AF, patients with cryptogenic stroke, or after AF ablation. The Confirm Rx ICM is the first smartphone-compatible ICM, allowing for app-based recording and transmission of ECGs for continuous remote monitoring of patients without a home-based transmitter. The purpose of the ongoing Confirm Rx SMART Registry is to assess the real-world safety and performance of the Confirm Rx ICM over a 12-month period. The primary safety endpoint is freedom from serious adverse device events (SADE) and serious adverse procedure-related events through 1-month post insertion.

Methods: This prospective multi-center registry will enroll approximately 2500 subjects in approximately 150 centers globally. After insertion, subjects have 1M in-clinic, 6M remote, and 12M in-clinic visits. Additional analyses include accuracy of device-detected arrhythmias, clinical actions taken, and quality-of-life assessments, among others. Only subjects with available data were analyzed.

Result: As of May 17, 2019, 360 subjects across 40 sites have enrolled in the study. Major indications for ICM implant included syncope (56.9%), AF (35.0%), risk for cardiac arrhythmias (23.9%), palpitations (23.6%), and dizziness (12.5%). Median R-wave amplitudes at insertion was 0.52 mV (IQR: 0.37, 0.79) with 69.4% (247/356) of ICMs oriented 45 degrees relative to the sternum and 21.6% (77/356) oriented parallel to the sternum. The primary endpoint analysis showed 100% freedom from procedure-related SAEs and 99.2% freedom from SADEs. Of the 3 SADEs, one patient received a pacemaker implant due to syncope. Device migration and false detection episodes were reported in the 2 other SADEs, resulting in device explant. After 1M of follow-up, a total of 170 subjects had EGM-associated device-detected episodes, 86 of which had device-detected AF episodes, 39 subjects with tachy episodes, 84 with brady episodes, and 113 with pause episodes. Additional diagnoses based on device-detected episodes were made in 5.1% (13/256) of patients, including diagnoses of AF, SVT, VT, PVC, among others. Various clinical actions resulting from device-detected episodes included medication management, pacemaker implant, and device reprogramming. Six and 12-month data will also be presented.

Conclusion: To-date, results from the Confirm Rx SMART registry have shown 100% freedom from procedure-related SAE's and >99% freedom from device-related SADEs after 1 month. The Confirm Rx ICM is the first ICM with continuous remote monitoring capabilities, due to a new monitoring paradigm.
offered through a smartphone. The current analysis includes devices with the previous Confirm Rx generation. Future analyses will compare results with the Confirm Rx SharpSense™ technology.