Evaluation of New Algorithm Enhancements to Improve Accuracy of Arrhythmia Detections in An Insertable Cardiac Monitor

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Introduction: Recent enhancements in Abbott Confirm Rx™ insertable cardiac monitor (ICM) arrhythmia detection algorithms (SharpSense™ Technology) aim to improve the positive predictive value for arrhythmia detection while maintaining high sensitivity. In this analysis, we sought to characterize the clinical performance of the newly developed SharpSense™ Technology.

Methods: De-identified device episodes from a set of Confirm Rx™ devices with complaints related to false episodes were extracted from Merlin.net patient care network for the evaluation. All episodes were manually adjudicated to determine if the episodes were true or false, then run through SharpSense™ algorithms.

Result: A total of 25,359 episodes (from 40 devices/3 clinics) were analyzed (pause: 19,107 [75%], bradycardia: 5,591 [22%] and atrial fibrillation (AF): 661 [3%]). Devices were implanted between May 2017 and Jan 2019 for syncope (60.0%), AF-related (21.4%), and other including cryptogenic stroke and palpitations (18.6%). Median duration of device follow-up was 116 days with an interquartile range of 39 days. SharpSense™ technology reduced false pauses, bradycardia, and AF episodes by 98.2%, 98.7%, and 49.5%, respectively, with 1.0%, 0.0%, and 0.0% reduction in true episodes, respectively. Overall reduction in false positive episodes was 96.9% while maintaining high relative sensitivity (compared to without SharpSense) of 99.7%.

Conclusion: This analysis demonstrates that the newly developed SharpSense™ algorithms significantly reduce false pause, bradycardia, and AF episodes with minimal reduction in true episode detection.