Effectiveness and Performance of Confirm Rx™ SharpSense™ Technology: A Multi-center Retrospective Analysis

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**Introduction**: With the intent of reducing false detections (while maintaining sensitivity), recent enhancements have been introduced to the Abbott Confirm Rx™ insertable cardiac monitor (ICM) arrhythmia detection algorithms (SharpSense™ Technology). However, the performance of these algorithm enhancements may vary at individual clinics depending on the implant indications, implant techniques, and device programming preferences, etc. In this analysis, we conducted a multi-center retrospective analysis to evaluate the effectiveness and performance variation of SharpSense technology.

**Methods**: Pause, bradycardia (brady), and atrial fibrillation (AF) episodes triggered and transmitted to Merlin.net™ patient care network by the Confirm Rx ICMs without SharpSense were analyzed using the enhanced detection algorithms. The enhanced algorithms reject pause and brady detection if undersensing of R waves contributed to the trigger and reject AF detection if presence of p-wave is found in the signal. Human adjudication combined with supervised machine learning of triggered and transmitted episodes was used as the reference for assessing the performance of these enhanced algorithms.

**Result**: A total of 294,416 episodes (512 devices/ 8 clinics) were analyzed (pause: 143,418 [61%], bradycardia: 70,250 [30%] and AF: 21,088 [9%]). The implant indications were syncope (27%), AF (42%), and other - cryptogenic stroke, palpitations, etc. (31%). Median device follow-up duration was 317 days with an interquartile range of 225 days. For the entire dataset, SharpSense reduced false pauses, brady, and AF episodes by 98.8%, 94.9%, and 45.7%, respectively, with 0.4%, 0.1%, and 1.4% reduction in true episodes, respectively. Overall reduction in false positive episodes was 97.8% with relative sensitivity (compared to without SharpSense) of 99.9%. In clinic-averaged, SharpSense reduced false pauses, brady, and AF episodes by 98.4±1.5%, 96.1±4.5%, and 45.4±12.5%, respectively, with 0.5±1.1%, 0.1±0.1%, and 1.1±1.6% reduction in true episodes, respectively.

**Conclusion**: The analysis demonstrates that the newly developed SharpSense™ algorithms significantly reduce false pause, bradycardia, and AF episodes with minimal reduction in true episode detection. The performance of SharpSense is highly consistent across individual clinics.