Event Rates with Confirm Rx™ SharpSense™ Technology using a Real-World Remote Monitoring Database

Christopher Piorkowski
Allison Connolly
Ignacio Reyes
Avi Fischer
Yelena Nabutovsky
Naushad Shaik
Roland Tilz
John Ip

Introduction: Insertable cardiac monitors (ICM) are effective in detecting arrhythmias. The new Confirm Rx™ ICM with SharpSense™ Technology uses an advanced algorithm to improve accuracy of bradycardia (brady) and pause detection. This study aims to characterize the impact of SharpSense™ on ICM-detected event rates in a large real-world cohort.

Methods: Patients implanted with the Confirm Rx™ ICM before June 2019 and who communicated at least one scheduled remote transmission in the Merlin.net™ remote monitoring system made up the study cohort. Event rates in the first 31 days post implant were compared in patients implanted with Confirm Rx with SharpSense™ and those without. Propensity score matching was used to minimize differences in patient characteristics between groups. Probability of having any events (>0) and of having a high number of events (>10/day) were compared with logistic regression and event rates with Poisson regression. Multivariate models were used to further adjust for differences between groups.

Result: Of the 23,781 patients who met inclusion criteria (62±17 years, 50% female, 78% US), 653 had devices with SharpSense™ and 23,128 did not. After matching, 581 had devices with SharpSense™ and 2324 did not. Devices with SharpSense™ had significantly lower brady (81 vs. 14 events, p<0.001) and pause (152 vs. 14 events, p<0.001) events compared to without. In addition, significantly fewer devices with SharpSense™ had any brady (Odds Ratio (OR)=0.35) or pause (OR=0.39) events compared to without (p<0.001) and a significantly lower incidence of detecting a high number of brady (OR=0.22) and pause (HR=0.10) events (p<0.001). In patients with detected events, significantly fewer events occurred with SharpSense™ (brady OR=0.49, pause OR=0.15, p<0.001).

Conclusion: In this patient cohort, SharpSense TM was associated with an 83% lower rate of brady events and 91% lower rate of pause events in the first 31 days post implant. This technology improves the data management of ICM-detected events by reducing false positive events and decreasing the overall event count.