Event Rates with Confirm RxTM SharpSenseTM 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 RxTM ICM with SharpSenseTM Technology uses an advanced algorithm to improve accuracy of bradycardia (brady) and pause detection. This study aims to characterize the impact of SharpSenseTM on ICM-detected event rates in a large real-world cohort.

**Methods**: Patients implanted with the Confirm RxTM 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 SharpSenseTM 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 SharpSenseTM and 23,128 did not. After matching, 581 had devices with SharpSenseTM and 2324 did not. Devices with SharpSenseTM 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 SharpSenseTM 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 TM (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.