Real-World Safety Profile of the EV ICD System

Insights from the MAUDE Database

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The first substernal and extracardiac defibrillation system, the extravascular implantable cardioverter-defibrillator (**EV ICD**), provides a novel technology that both allows effective defibrillation at similar energy to intracardiac devices and allows anti-tachycardic pacing, all without the risks of inherent to transvenous systems. The recently published long-term outcomes of the Extravascular Implantable Cardioverter-Defibrillator (EV ICD) Pivotal Study shows promising results, with follow-up data up to 3 years. P. Friedman *et al.* [1] found that the EV ICD system provided 100% termination of discrete spontaneous ventricular arrhythmias, with no major intraprocedural or ICD complications from implant to final follow-up, with an overall freedom of related complications of 89% at 3 years [1].

Clinical trials however often represent best-case scenarios, with both experienced operators in a controlled setting with careful patient screening and selection. We analyzed post-market surveillance data from the U.S. Food & Drug Administration (**FDA**) Manufacturer and User Facility Device Experience (**MAUDE**) Database, which provides voluntary reporting for medical devices from health care professionals and mandatory reporting from manufacturers. We searched for reports from the October 23, 2023, the date of FDA approval of the *Aurora EV ICD* system, to December 31, 2024, that were related to either the device itself or the *Epsila* lead. We manually adjudicated each report and categorized events into device-specific complications, including mortality, inappropriate therapies, sensing issues, procedural complications, and infections.

The MAUDE data contains 246 independent event reports from 2023-10-23 to 2024-07-22. Of the event reports, 123 (50%) were indicated to have been part of a clinical study. The most common issue found was oversensing, with 126 (51%) reports of issues with P and T wave oversensing, along with noise that led to the false detection of ventricular arrhythmias. The oversensing and noise issues were associated with 32 (13%) reports of inappropriate shocks, as well as due to supraventricular arrhythmias that fell into the the ventricular therapy zones. Operators noted at least 48 (20%) times that the device had to be repositioned due to difficulty manipulating hte lead, abnormal sensing, or difficulty in device programming due to noise or position. The lead became dislodged or migrated during follow-up for 8 (3%) patients, and there were 19 (8%) reports of superficial or deeper infections. The listed reasons led to 21 (9%) device explantations. During initial implant, pericardial damage or laceration occurred 9 (4%) times, along with pneumothorax and pneumomediastinum 12 (5%). There were 4 (2%) mortality events, none of which were due to failure of cardioverter/defibrillator therapy. The relative frequency of these events are seen in Figure 1.

We can not compare directly the frequency of events seen in the *Pivotal* trial, but we can see the most common issues that may arise in a real-world practice and novel issues that have not yet been reported. We can also extrapolate the frequency of events to the likely number of procedures performed during the first year of this device's approval, and herald the rates to come as the technology is utilized by early-adopters. Sensing was the predominant issue, with the majority of reports noting noise, double-counting, and atrial oversensing, with 1 out of 5 of these events resulting in inappropriate shocks. Importantly, we found procedural complications such as pericardial damage or laceration, mediastinal damage, and pneumothoraces to be an infrequent but present fraction of event reports, including at least once case of cardiac tamponade requiring pericardiocentesis. The *Pivotal* trial reported no pneumothoraces or pericardial effusions, in comparison. As a comparator, a nation-wide study by R. E. Kirkfeldt, J. B. Johansen, E. A. Nohr, O. D. Jørgensen, and J. C. Nielsen [2] showed that over 1 year, had 562 complications out of 5918 implants. Out of all complications, they showed 16% were pneumothoraces, 21% were superficial and deep wound infections, 7% were cardiac perforations, and 3% were lead dislodgements. The MAUDE data is limited to voluntary reporting and lacks the total implant denominator to understand incidence, and moreso reflects the early adoption experience and not reflect long-term performance with increased operator expertise.

Our findings highlight the importance of post-market surveillance and suggest that the safety profile of the EV ICD is not yet well-defined for general implementation. We believe this data should inform shared decision-making and discussion between physicians and patients as the EV ICD disseminates into broader clinical use.

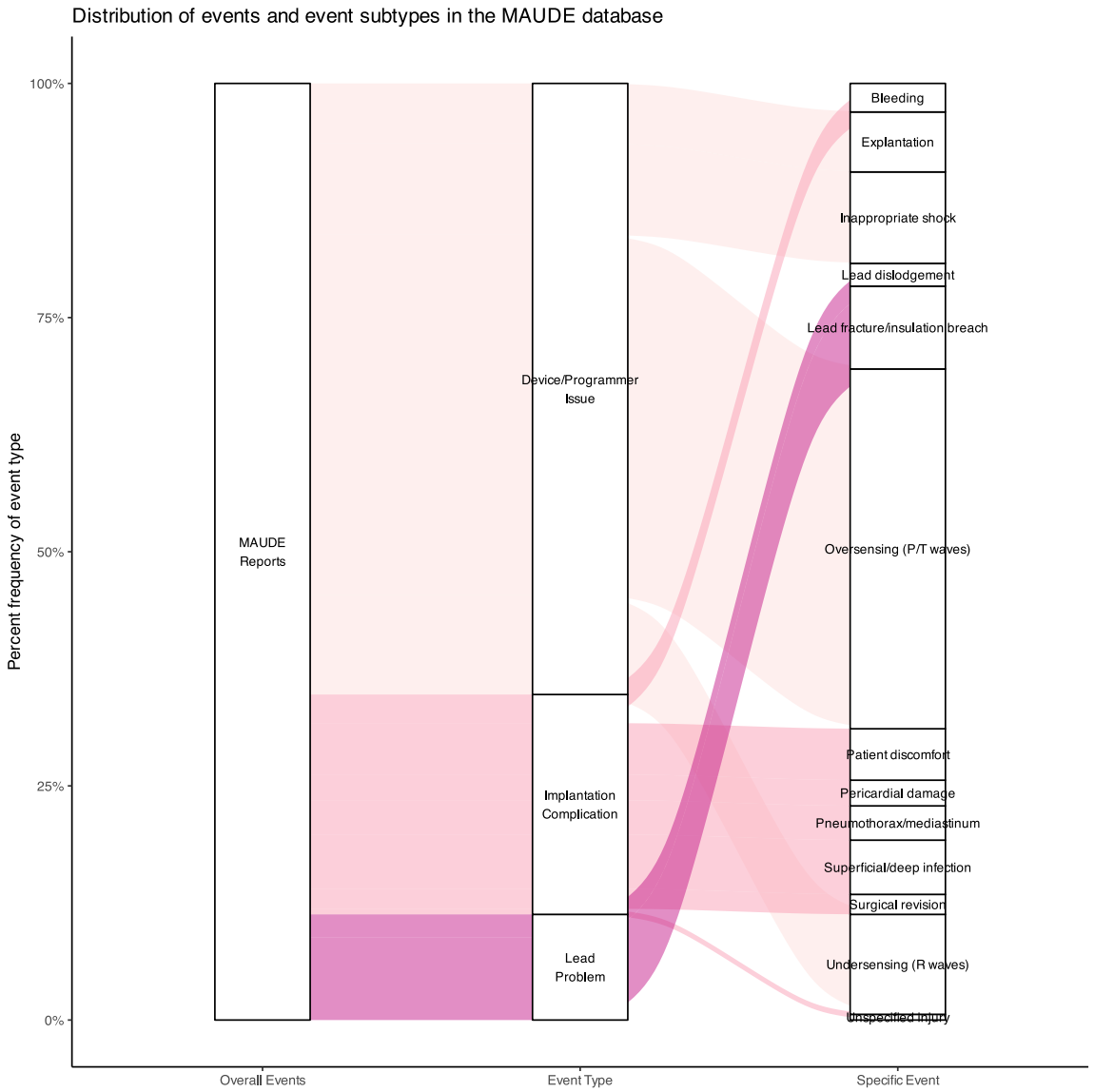

Figure 1: Breakdown of Procedural Complications Reported from the MAUDE Database. The figure breaks down the frequency and summary of key complication reports seen in the MAUDE database for the EV-ICD generator and lead.

Bibliography

[1] P. Friedman *et al.*, "Performance and Safety of the Extravascular Implantable Cardioverter-Defibrillator Through Long-Term Follow-Up: Final Results From the Pivotal Study," *Circulation*, Sep. 2024, doi: 10.1161/CIRCULATIONAHA.124.071795.

[2] R. E. Kirkfeldt, J. B. Johansen, E. A. Nohr, O. D. Jørgensen, and J. C. Nielsen, "Complications after Cardiac Implantable Electronic Device Implantations: An Analysis of a Complete, Na-

tionwide Cohort in Denmark," *European Heart Journal*, vol. 35, no. 18, pp. 1186–1194, May 2014, doi: 10.1093/eurheartj/eht511.