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Periprocedural outcomes from the postmarket study of the extravascular implantable cardioverter-defibrillator: Preliminary Enlighten study results and meta-analysis

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ABSTRACT

BACKGROUND Premarket clinical trials have shown the extravascular implantable cardioverter-defibrillator (EV-ICD) system to provide effective therapy with a low complication rate, but its performance in the real world is unknown.

OBJECTIVE We report on the periprocedural safety and performance of the EV-ICD system from the postmarket Enlighten (EV-ICD Post-Approval Registry) Study.

METHODS Enlighten is an ongoing, global, prospective, postmarket registry study, enrolling patients guideline indicated for an ICD with a planned implantation of the Aurora EV-ICD system (Medtronic, Mounds View, MN). Procedure characteristics and outcomes, defibrillation testing details, system- or procedure-related major complications, electrical measurements, and pacing therapy programming through discharge were analyzed. A meta-analysis of premarket EV-ICD studies is included in the Supplemental Material for comparison with postmarket Enlighten Study data.

RESULTS In total, 228 Enlighten patients underwent an Aurora EV-ICD implant attempt (49.4 ± 15.4 years old; 27.9% female; 43.5 ± 16.1 mean left ventricular ejection fraction). Tunneling and substernal lead placement were successful in 227 of 228 (99.6%) patients. After electrical testing, 221 (96.9%) patients remained implanted with the EV-ICD and proceeded to follow-up. Defibrillation testing, if performed, was successful in 191 of 193 (99.0%) patients. The rate of system- or procedure-related major complications at discharge was 3.9%. Electrical measurements were stable at discharge.

CONCLUSION In a global, real-world cohort, the EV-ICD system demonstrated a high success rate for terminating induced ventricular arrhythmia episodes at implant and a low rate of periprocedural major complications at discharge, comparable with the premarket experience.

CLINICALTRIALS.GOV ID NCT06048731 (Enlighten Study: The EV-ICD Post-Approval Registry)

KEYWORDS Defibrillation testing; Extravascular implantable cardioverter-defibrillator; Postapproval; Sudden cardiac death; Ventricular tachycardia/fibrillation

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Introduction

In patients at risk for ventricular arrhythmias, implantable cardioverter-defibrillators (ICDs) have been shown to reduce mortality.[1,2] To avoid potential lead-related complications from transvenous ICD implantation, the subcutaneous ICD (S-ICD) system was introduced (current model: EMBLEM MRI S-ICD [Boston Scientific, Marlborough, MA]).[3] Although this device reduces lead-related complications, it does not provide antitachycardia pacing (ATP) and requires a larger device for higher energy shocks.[4] The extravascular ICD (EV-ICD)

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system (current model: Aurora EV-ICD [Medtronic, Mounds View, MN]) was developed to provide a device similar in size to transvenous ICDs that could deliver ATP therapy and lower energy shocks while also avoiding the vasculature.[5,6]

The safety and efficacy of the EV-ICD system were assessed in the small Pilot Study (N = 21), the large, global Pivotal Study (N = 316) and the Continued Access Study (N = 33), with published data from the Pilot and Pivotal studies.[5–8] However, the market-released Aurora EV-ICD system has yet to be evaluated in the real world. Enlighten, a prospective, postmarket registry study, was designed to assess the safety and performance of the Aurora EV-ICD system in real-world clinical practice. The EV-ICD implant procedure is a relatively novel procedure for many implanters; therefore, this analysis serves to provide an assessment of real-world periprocedural outcomes with the postmarket EV-ICD system.

Methods

Study design

The Enlighten (The EV-ICD Post Approval Registry) Study design has been described in detail previously.[9] Briefly, Enlighten (Clinical Trial Registration Number: NCT06048731) is a prospective, global, postmarket registry enrolling patients intending to receive an EV-ICD system. Subjects from premarket EV-ICD studies (Pilot, Pivotal, Continued Access) had the option of enrolling into the Enlighten Study for continued follow-up. However, this current Enlighten Study analysis includes only newly enrolled postmarket patients implanted with the Aurora EV-ICD system (Medtronic) and does not include those patients who carried forth from premarket studies. The Enlighten Study complied with the Declaration of Helsinki, with patients providing informed consent before participation, and the research protocols approved by locally appointed ethics committees in accordance with local requirements.

Aurora EV-ICD system

The Auora EV-ICD system is an extravascular cardioverter-defibrillator with a lead that is implanted in the substernal space outside the heart. The Aurora EV-ICD is intended to be implanted by electrophysiologists who have received appropriate training on the procedure, with their first five implants being proctored by a cardiac surgeon. The generator (volume 33 cm^3) has a Physiocurve (Medtronic) design that is connected to an epsilon-shaped lead (Figure 1). The system has the ability to provide defibrillation (maximum output: 40 joules [J]), ATP, pause-prevention pacing, and postshock pacing therapies. The Aurora EV-ICD device differs from the device implanted in premarket studies (Pilot, Pivotal, and Continued Access), most notably the addition of a novel P-wave oversensing discriminator (Smart Sense) to reduce inappropriate shock. Also, the substernal lead underwent manufacturing enhancements before the Aurora EV-ICD commercial launch.

Abbreviations

ATP: antitachycardia pacing

CI: confidence interval

EV-ICD: extravascular implantable cardioverter-defibrillator

ICD: implantable cardioverter-defibrillator

LVEF: left ventricular ejection fraction

S-ICD: subcutaneous implantable cardioverter-defibrillator

SSVA: sustained shockable ventricular arrhythmia

Objectives

The main objective of this analysis was to assess the acute periprocedural safety of the Aurora EV-ICD system in newly implanted patients enrolled in the Enlighten Study. Rates of system- or procedure- related major complications through discharge are reported. If discharge date was unavailable, events through 30 days postprocedure were considered. Major complications are defined as those resulting in 1 or more of the following: death, hospitalization, prolongment of hospitalization by $\geq$48 hours, permanent loss of defibrillation function caused by device dysfunction, or system revision (reposition, replacement, explant). All major complications were adjudicated by an independent clinical events committee. Tunneling and substernal lead placement success and the rate of patients who proceeded to follow-up after electrical testing were evaluated. Other measurements included implant procedure duration (first incision to final suture), defibrillation testing success, therapy programming at pre-hospital discharge, and electrical values taken at implant (R-wave amplitude, pacing capture threshold, impedance). A meta-analysis, showing these same data points across the premarket EV-ICD studies and comparing a pooled premarket cohort (including Pilot, Pivotal, and Continued Access patients) with the Enlighten cohort, is provided in the Supplemental Material.[5,8]

Defibrillation testing

The Enlighten Study captures real-world clinical data, and although the study does not require defibrillation testing at implant or specify the energy at which defibrillation testing should be conducted, data are collected when performed. The overall success rate of defibrillation testing, regardless of energy, is reported. We also report minimum successful energy and minimum energy tested for all Enlighten defibrillation tests. A detailed description of the defibrillation testing protocol used during the premarket studies is provided in Supplemental Methods.

Statistical analysis

Descriptive statistics are reported as the mean with standard deviation for continuous variables and frequency with percentage of total patients for categorical variables. All statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC).

Results

Baseline characteristics

In total, 228 Enlighten patients had an implant attempt, performed by 81 different implanters across 19 countries.

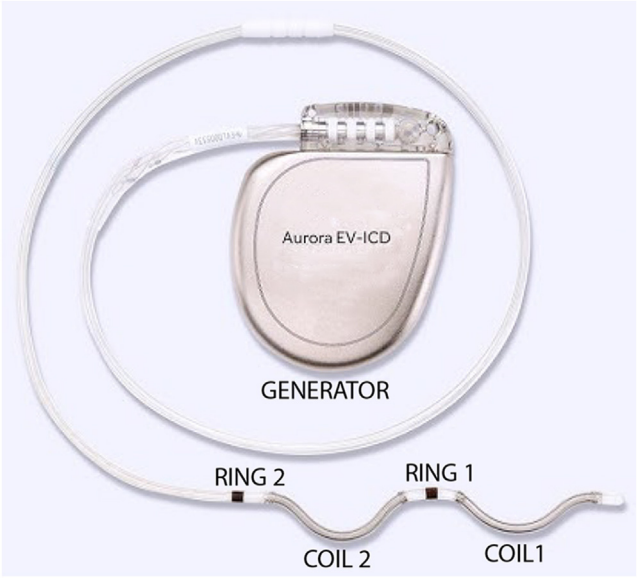

Figure 1
Aurora EV-ICD system. Image depicting the Aurora EV-ICD system, with the ring and coil locations labeled. EV-ICD = extravascular implantable cardioverter-defibrillator.

Enlighten patients had a mean age of 49.4 ± 15.4 years, a mean left ventricular ejection fraction (LVEF) of 43.5 ± 16.1, and rates of 67.3%, 22.6%, and 33.2% for cardiomyopathy, coronary artery disease, and hypertension, respectively (Supplemental Table 1).

Implant procedure and defibrillation testing outcomes

Tunneling and substernal lead placement was achieved in 99.6% (227 of 228) of the Enlighten patients with an implant attempt. Following successful lead placement and subsequent electrical testing, 221 of 228 (96.9%) Enlighten patients proceeded to follow-up, with inadequate R-wave sensing being the most common reason reported for not continuing (n = 6). The mean procedure time from first incision to final suture, which included defibrillation testing when performed, was 84.9 ± 43.5 minutes.

Defibrillation testing at implant was performed in 194 of 228 Enlighten patients, not performed in 20, and data for the remaining 14 were not available at the time of data snapshot. The most common justifications given for not performing defibrillation testing at implant were as follows: patient had a precluding condition (n = 8), testing was planned for a later date (n = 5), and unable to induce (n = 4). Defibrillation testing outcomes were known for 193 Enlighten patients, of which 191 (99.0%) were successful and two (1.0%) unsuccessful; the result was unknown for one patient. The minimum energy tested and the minimum energy at which success was observed are shown in Figure 2. Although premarket clinical studies recommended a 10-J safety margin during defibrillation testing, in the Enlighten study, maintaining a safety margin during defibrillation testing was left to physician discretion (maximum output of the EV-ICD device is 40 J).

Periprocedural major complications

The rate of EV-ICD system- or procedure-related major complications at discharge was 3.9% for Enlighten patients. The most common system- or procedure-related major complications were lead dislodgement (n = 2, 0.9%) and pneumothorax (n = 2, 0.9%) with single occurrences of all other events (Table 1). There were no cases of mediastinitis, endocarditis, or tamponade related to the system or procedure in either cohort, and none of the procedures required major surgical intervention or sternotomy.

Electrical values and programming at discharge

Pacing capture threshold, R-wave amplitude, or impedance measurements were gathered for 208 (94.1%) Enlighten patients at implant. The mean pacing capture threshold at Ring 1–Coil 2 was 5.4 ± 2.1 volts (n = 137), mean R-wave amplitude at Ring 1–Ring 2 was 2.9 ± 1.7 millivolts (n = 205), and mean impedance at Ring 1–Ring 2 was 429.4 ± 190.6 ohms (n = 202) (Supplemental Figure 1). The Aurora EV-ICD system is shipped with ATP and postshock pacing programming nominally "off," although pause-prevention pacing is nominally in monitor mode. At discharge, among those for whom programming was reported, the proportion of patients with ATP, postshock pacing, and pause-prevention pacing programmed "on" was 71.8% (148 of 206), 84.8% (173 of 204), and 20.0% (39 of 195), respectively.

Discussion

This is the first reported real-world evaluation of the Aurora EV-ICD, providing periprocedural outcomes from the Enlighten postmarket study. Tunneling and substernal lead placement was attained in 99.6% of Enlighten implants with a high rate of defibrillation testing success (99.0%) in those for whom it was performed. The rate of major system- or procedure-related complications through discharge was low (3.9%), demonstrating the implant procedure to be safe in a real-world setting. Electrical measurements taken at implant were stable, and more than 70% had ATP therapy programmed "on" at discharge.

The EV-ICD lead is implanted in a unique position: below the sternum adjacent to myocardial tissue. Given that this location is new for implanters, hands-on training is required for those who wish to implant the EV-ICD device in patients. As shown by the outcomes in this post-approval Enlighten cohort, the implant procedure remained safe and successful across an expanded range of implanters (81 in 19 countries). These results speak to the quality and effectiveness of the EV-ICD implant training program.

Demographically, the Enlighten cohort is comparable with what has been shown in premarket EV-ICD studies, but a number of characteristics were statistically different for Enlighten compared with premarket studies (Supplemental Table 2). Patients implanted with Aurora EV-ICD systems in Enlighten were younger (49.4 vs 53.4 years old, on average; $P < .001$) and overall healthier than what was seen in the premarket studies (higher LVEF, $P = .004$; less cardiomyopathy, coronary

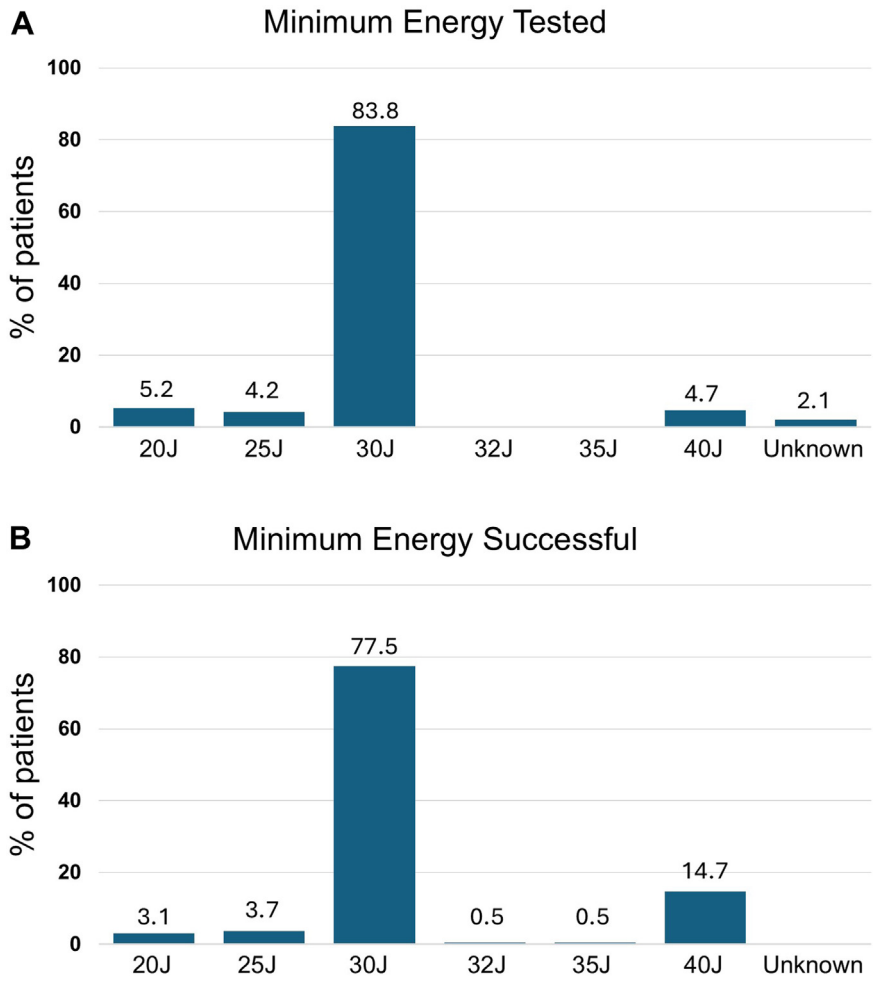

Figure 2
Distribution of energies used for defibrillation testing in Enlighten. Bar graphs depicting the distribution of patients across minimum energies tested (**A**) and the minimum energies at which testing was a success (**B**) during defibrillation testing at implant. The EV-ICD system has a maximal defibrillation energy of 40J, and not all patients were tested with a safety margin; success at 40J may have been the only energy tested. J = joules. Other abbreviation as in Figure 1.

artery disease, or hypertension, $P < .001$ for all). A mean LVEF of 43.5% seen for Enlighten is higher than common guideline indications cutoff of ≤35%. This trend could indicate that—in the real world—the EV-ICD system is being implanted more frequently in younger patients with inherited conditions that put them at risk for ventricular arrhythmias. As such, the Enlighten cohort may be more prone to ventricular fibrillation, resulting in less use of ATP therapy, a major feature of the EV-ICD. By comparison, both the Enlighten and the premarket EV-ICD patients are younger and healthier compared with the typical ICD population.[10] The S-ICD study populations have also trended toward being healthier and younger than typical ICD patients, but patients in the S-ICD postapproval study were older, with lower LVEFs, and more comorbidities on average, compared with the premarket S-ICD studies.[11]

Table 1 System- or procedure-related major complications through discharge for the Enlighten Study

Adverse event	Number of events at discharge*; number of events (N, %) Enlighten Study (N = 228)
Device dislocation	1 (1, 0.4%)
Device inappropriate shock delivery	1 (1, 0.4%)
Implant site pain	1 (1, 0.4%)
Lead dislodgment	2 (2, 0.9%)
Pneumoperitoneum	1 (1, 0.4%)
Pneumothorax	2 (2, 0.9%)
Pulmonary embolism†	1 (1, 0.4%)
Total	9 (9, 3.9%)

*Or within 30 days of implant for those patients where discharge date not available.
†Pulmonary embolism occurred in one Enlighten patient with a history of deep vein thrombosis, with a possible relationship to anesthesia and length of procedure.

Mean procedure time for Enlighten implants was 84.9 ± 43.5 minutes, which is longer than the 76.0 ± 32.7 minutes average time reported for the premarket EV-ICD studies (Supplemental Table 3). The difference in procedure time may be a result of several factors, including differences in defibrillation testing, the number of implanters (81 in Enlighten vs 59 in premarket), and the number of tunneling attempts. Following Pivotal trial experience, EV-ICD implant training stressed adjusting lead placement for optimal sensing, which may be resulting in more tunneling attempts in Enlighten. For

context, the mean procedure time for an S-ICD implant was reported to be 77.3 ± 36.2 minutes during its postapproval study.[4,11] Tunneling and lead placement into the mediastinal space was achieved in 99.6% of Enlighten implant attempts and 99.7% of attempts in premarket studies (Supplemental Table 3). Furthermore, the number of patients who proceeded to follow-up with a device still implanted was higher in Enlighten (96.9%) than in the premarket studies (93.8%). All of these results demonstrate the ability of implanters to consistently access this space for lead placement given the proper training.

Defibrillation testing was considered successful in 99.0% of Enlighten patients who underwent testing, compared with 97.7% defibrillation testing success across all premarket EV-ICD trials according to study protocols (Supplemental Table 4). The premarket Pilot, Pivotal, and Continued Access Studies required defibrillation testing success with two consecutive 30-J shocks (or a single 20-J shock) for the implant to be labeled a success, providing at least a 10-J safety margin (40-J maximum energy of the device). However, in the real-world setting, physicians may be more likely to perform fewer inductions during the implant procedure or exercise discretion with regard to safety margin, especially in patients deemed to have no alternative options for ICD placement or for whom defibrillation testing would be hazardous.

The rate of system- or procedure-related major complications at discharge was 3.9% in Enlighten, which was not statistically different from the rate at discharge compared with the pooled premarket cohort (2.4%; $P = .329$). These rates are similar to the 3.2% complication rate at discharge reported for transvenous systems from a large registry, suggesting an early signal that EV-ICD implant safety is comparable with the current standard of care.[12] Premarket EV-ICD studies excluded individuals with an LVEF <20%, which may have affected the incidence of complications. Although the major complication rates at discharge were similar between Enlighten and premarket cohorts, the types of complications differed (Table 1 and Supplemental Table 5). The Enlighten study has observed several major complications not observed during the premarket studies (inclusive of all follow-up): most notably, two cases of pneumothorax and a pneumoperitoneum, all of which were resolved without sequelae. The case of pneumoperitoneum was identified via imaging after the patient developed abdominal pain; it resolved spontaneously a few hours after intervention, with air ingress through the subxiphoid incision and the introducer identified as the likely cause. Two cases (0.9%) of pneumothorax were a result of lead placement in the pleural cavity without injury to the lung; both were clinically insignificant (identified through imaging one day postprocedure) and required no intervention. Comparatively, pneumothorax rates have been reported at 0.9% with transvenous systems and 0.1% with subcutaneous systems.[13,14]

A single major intraprocedural complication occurred in Enlighten (one of the aforementioned pneumothorax events). This event required no further intervention and was classified as a major complication caused by the prolongation of hospitalization postprocedure. Further, none of EV-ICD implant procedures in Enlighten required cardiac intervention. This is consistent with the Pilot and Pivotal studies, in which no major intraprocedural complications were reported.[5,6]

Limitations

There were limitations to this analysis that must be considered. The Enlighten results only display outcomes through discharge, and so longer-term comparisons as well as rates of appropriate and inappropriate therapy for spontaneous arrhythmias will be needed as Enlighten accumulates more follow-up time. In addition, not all patients who have received postmarket Aurora EV-ICDs are enrolled in the Enlighten study, and so these data may not be totally representative of the cumulative physician and patient experience in the real world. Comparisons between Enlighten and premarket cohorts in the Supplemental Material are limited by the differences in study design, particularly defibrillation testing protocols and the controlled environment of a premarket clinical trial, relative to real-world experience. Finally, as previously discussed, the Enlighten cohort represents a younger, healthier population than the average ICD patient, and so evaluation of the EV-ICD in older patients with more comorbidities may be warranted.

Conclusion

In a global, real-world, prospective analysis of acute outcomes with the EV-ICD system, we show that the device can be implanted with a low rate of periprocedural complications and high defibrillation success for induced episodes. These results are in line with what was shown during premarket studies.

Appendix. Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2025.02.012.

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Data availability: Data cannot be shared for ethical/privacy reasons.

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