Medtronic

Engineering the extraordinary

The Global Extravascular Implantable Cardioverter Defibrillator (EV ICD™) Pivotal Study

Overview

The global Extravascular Implantable Cardioverter Defibrillator (EV ICD) Pivotal Study assessed the safety and effectiveness of the Medtronic EV ICD™ System for patients at risk of sudden cardiac death. The EV ICD system is a first-of-its-kind defibrillator with the lead placed under the breastbone, outside of the heart and veins.

The EV ICD system is designed to treat dangerously fast heart rhythms that can lead to sudden cardiac arrest (SCA). Clinical trial participants received the same therapies provided by traditional ICDs, including defibrillation, anti-tachycardia pacing (ATP, which paces the heart to interrupt and terminate a dangerous rhythm, potentially avoiding a defibrillation shock), and back-up pacing therapies with this single implanted device that is similar in size, shape, and longevity to traditional, transvenous ICDs.

The results of the EV ICD Pivotal Study, presented as late-breaking science at the European Society of Cardiology (ESC) Congress 2022, found the EV ICD system achieved a defibrillation success rate of 98.7% and met its safety endpoints in a global clinical trial.[1] The results were simultaneously published in *The New England Journal of Medicine*.

Study Design

- The EV ICD pivotal study was a prospective, multicenter, single-arm, non-randomized, pre-market clinical study.
- The study's primary effectiveness endpoint was defibrillation testing success rate at implant.
- The primary safety objective was freedom from major system and/or procedural complications at six months after implant.

Patient Selection and Follow-Up[1]

- The EV ICD pivotal study enrolled 356 patients at 46 sites in 17 countries in North America, Europe, the Middle East, Asia, Australia and New Zealand.
    - A total of 299 patients received an implanted system.
- The study included patients with a Class I or IIa indication for an ICD.
- Patient exclusions: prior sternotomy, chronic pacing indication (including CRT), and those unable to undergo defibrillation testing.
- The enrolled study patient population was 75% male and 25% female, ages 54 +/- 13.
- Patients were followed for an average of 10.6 months.

Study Results: Effectiveness[1]

In the study, the device's effectiveness in delivering defibrillation therapy at implant was 98.7% (298 of 302 patients), surpassing the prespecified performance goal of 88%, reflecting a greater defibrillation efficacy at implant for the EV ICD than historical transvenous ICD studies,[2-5] and comparable efficacy to the subcutaneous ICD despite a smaller device size.[6]

- All discrete spontaneous arrhythmias were successfully treated (18 of 18, 100%).

- Further, the efficacy of ATP – which paces the heart to interrupt and terminate a dangerous rhythm, potentially avoiding a defibrillation shock – in the EV ICD study was comparable to ATP efficacy in transvenous defibrillators.[7,8]
    - In total, 33 shocks were avoided by having ATP programmed "on."

Study Results: Safety[1]

The study exceeded its safety endpoint: at six months, 92.6% of patients (Kaplan-Meier estimate) were free from major system and/or procedure-related major complications such as in hospitalization, invasive intervention or death (compared to the pre-specified performance goal of 79%; $p<0.001$).

- There were no major intraprocedural complications.
- There were no unique complications observed related to the EV ICD procedure or system (compared to transvenous and subcutaneous ICDs).
- At six months, 25 major complications were observed in 23 of 316 patients who underwent an implant attempt (7.3%).
- Twenty-nine patients experienced inappropriate shocks (9.7%, average 10.6 months follow up).

Safety and effectiveness results were sustained out to 18 months.[9]

About the Medtronic EV ICD System

The Medtronic EV ICD system is designed to treat dangerously fast heart rhythms that can lead to SCA, while avoiding certain risks of traditional, transvenous ICDs because its lead (thin wire) is placed outside the heart and veins, under the breastbone (sternum) using a minimally invasive approach. Placing the lead in this location helps avoid long-term complications that may be associated with leads in the heart and veins, such as vessel occlusion (narrowing, blockage or compression of a vein) and risks for blood infections. The lead is connected to a device that is implanted below the left armpit (in the left mid-axillary region).

The Medtronic Aurora EV-ICD™ MRI SureScan™ (Extravascular Implantable Cardioverter-Defibrillator) received FDA approval and CE Mark in 2023.

About Sudden Cardiac Arrest (SCA)

SCA is a sudden, abrupt loss of heart function. Most SCA episodes are caused by the rapid and/or chaotic activity of the heart known as ventricular tachycardia (VT) or ventricular fibrillation (VF). These are abnormalities of the heart's electrical conduction system.

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