Medtronic News

Medtronic Extravascular ICD global clinical trial results reinforce device safety and effectiveness

Late-breaking data at Heart Rhythm 2023 underscore performance of first-of-its-kind investigational defibrillator with the lead placed under the breastbone, outside the heart and veins

Additionally, real-world analysis confirms long-term therapeutic benefit of commercially available ICDs

DUBLIN and NEW ORLEANS, May 20, 2023 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, announced longer-term follow-up results of its investigational EV ICD™ System, designed to treat dangerously fast heart rhythms that can lead to sudden cardiac arrest. Findings from the Extravascular Implantable Cardioverter Defibrillator (EV ICD) Pivotal Study, including patients followed through an average of 17.1 months, were presented as late-breaking science at Heart Rhythm 2023 in New Orleans. *The EV ICD system is investigational and not yet approved for sale or distribution in the United States.*

The Medtronic EV ICD system is a first-of-its-kind implantable defibrillator, designed to avoid certain risks of traditional, transvenous ICDs because its lead (thin wire) is placed outside the heart and veins, under the sternum (breastbone). The system offers anti-tachycardia pacing (ATP), pause prevention pacing, and a device similar in size, shape, and battery longevity to transvenous ICDs. Using a minimally invasive approach, the device is implanted below the left armpit (in the left mid-axillary region).

"The findings from the EV ICD pivotal study confirm that this system provides the advantages of a device with the lead outside the heart, and continues to provide pause prevention pacing and anti-tachycardia pacing to avoid shocks with prolonged follow up," said Paul Friedman, M.D., cardiac electrophysiologist and chair of the Department of Cardiology at Mayo Clinic in Rochester, Minn., and principal investigator of the Extravascular ICD pivotal study. "The EV ICD system is the first to include all of this functionality in a single extravascular device."

Study Results: Effectiveness

The study found that of the 299 implanted patients (average follow up 17.1±6.4 months), an estimated 6.8% (Kaplan-Meier estimate) of patients experienced appropriate therapy by 18 months, with 19 patients experiencing 80 spontaneous, appropriately treated arrhythmic episodes. Of discrete episodes treated with shock, 21/21 (100%) were successfully terminated. ATP successfully treated 35/52 episodes (67.3%). Shocks were avoided in nearly half of all spontaneous episodes because of the availability of ATP. These chronic data build on the EV ICD system's previously reported defibrillation effectiveness results at implant (98.7%).[1]

Study Results: Safety

The rate of freedom from major EV ICD system-or procedure-related complications through 18 months was 91.9% (Kaplan-Meier estimate). The most common major complication was lead dislodgment (10 events in nine patients) identified 0 to 120 days post-implant, predominantly related to the lead-anchoring technique. Inappropriate shocks occurred in 35 patients through all follow-up, with a rate of 10.2% (Kaplan-Meier estimate) at one year. Medtronic previously reported exceeding its safety endpoint at six months.[1]

Also, during Heart Rhythm 2023, data were presented leveraging EV ICD pivotal study device-detected episodes, demonstrating the Medtronic proprietary algorithm designed to reduce the number of inappropriate shocks successfully withheld inappropriate therapy caused by P-wave oversensing, the most common cause of inappropriate shocks, without compromising appropriate therapy. The algorithm reduced inappropriate

detection due to P-wave oversensing by 57%.

Contemporary ICD Benefit: A Real-World Analysis

ICDs are highly effective in providing life-saving therapy for patients at risk of sudden cardiac arrest, an electrical problem with the heart stemming from a dangerously fast heart rate (ventricular tachycardia or ventricular fibrillation) yet are still underutilized. At Heart Rhythm 2023, Anne B. Curtis, M.D., presented findings from a new analysis of commercially available devices showing 45% of ICD patients receive appropriate therapy for ventricular tachyarrhythmias through seven years.

"Within the medical community, referral for ICD therapy is being delayed in light of newer classes of heart failure medications, but this study shows that patients do receive needed therapy from their ICDs," said Dr. Curtis, SUNY Distinguished Professor, Department of Medicine, Jacobs School of Medicine & Biomedical Sciences, University at Buffalo. "This study gives physicians a contemporary view into the real-world impact of ICDs nationwide, underscoring the importance of indicated patients receiving these potentially life-saving devices."

The analysis included real-world, de-identified data from the Medtronic CareLink™ Network from 2013 to 2022, assessing time-to-first therapy in a contemporary cohort of ICD patients. First-time ICD recipients (225,444 patients, of which 179,638 were primary prevention) implanted with a Medtronic Evera™ or Visia™ single- or dual-chamber ICD were included. The study assessed time-to-first shock, ATP therapy, and any therapy (shock or ATP) for all patients, and also by primary- and secondary-prevention indications. At seven years post-implant, the incidence of any appropriate therapy for all patients was 45%, and 43% for primary prevention patients (patients who have not previously experienced a life-threatening arrhythmia).

"The expansive data on Medtronic ICDs presented at Heart Rhythm 2023 reinforce the impact these therapies have for patients at risk of life-threatening heart rhythms," said Alan Cheng, M.D., chief medical officer of the Cardiac Rhythm Management business, which is part of the Cardiovascular Portfolio at Medtronic. "Collectively, these findings demonstrate our unparalleled commitment to providing innovative solutions that improve patient experiences and outcomes even as medical care advances."

About the EV ICD Pivotal Study

The EV ICD Pivotal study is a prospective, multicenter, single-arm, non-randomized, pre-market clinical study that assessed the safety and effectiveness of the Medtronic EV ICD system for patients at risk of sudden cardiac death. It enrolled 356 patients at 46 sites in 17 countries in North America, Europe, the Middle East, Asia, Australia and New Zealand, and results were published in *The New England Journal of Medicine.* Medtronic has received CE (*Conformité Européenne*) Mark for the Aurora™ EV ICD system, and has secured FDA approval to conduct a Continued Access Study while the agency reviews the company's related pre-market device application.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 90,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all

those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for all. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

[1] Friedman P, Murgatroyd F, Boersma LVA, et al. Efficacy and Safety of an Extravascular Implantable Cardioverter-Defibrillator. N Engl J Med 2022; 387:1292-1302.

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