MAY 19, 2023

Medtronic PulseSelect Pulsed Field Ablation System Results in Low Atrial Arrhythmia Burden for AFib Patients

Heart Rhythm 2023: Late-breaking analysis of the PULSED AF Trial reveals first of its kind significant, meaningful quality of life improvements and healthcare utilization benefits of the PulseSelect Pulsed Field Ablation System

Medtronic today announced findings from a secondary analysis of the PULSED AF study, demonstrating positive results for the Medtronic PulseSelect™ Pulsed Field Ablation (PFA) System including atrial arrhythmia (AA) burden reduction, which correlated to improved quality of life and decreased healthcare utilization. In the study, 87% of paroxysmal (PAF) and 82% of persistent (PsAF) AF patients experienced less than 10% of AA burden[1]. The results were presented as late-breaking trial science at Heart Rhythm 2023 and published in *Heart Rhythm*.

PULSED AF is the first and only completed, global, and multi-center US FDA IDE clinical study for a PFA system and valuated the safety and effectiveness of the PulseSelect™ system for AF ablation. Results of PULSED AF were first presented as late-breaking science at ACC.23/WCC in March, demonstrating the study exceeded its safety and efficacy performance goals.

“These are first of its kind results for PFA technology, moving us beyond the traditional binary efficacy endpoint to a more holistic picture of patients’ arrhythmia experience. Most novel is that this study shows us that treatment with the Medtronic PulseSelect PFA System results in low burden, which we know supports significant quality-of-life improvements and is something clinicians and patients consider when choosing a treatment option,” said Atul Verma, M.D., electrophysiologist and director, Division of Cardiology, McGill University Health Centre in Montreal and principal investigator (PI) for the PULSED AF study.

AF Burden Findings

Traditionally defined as episodes of AA lasting at least 30 seconds, recurrence of known episodic AA is dependent on the monitoring strategy used. In the rigorously monitored PULSED AF study, burden was calculated for every patient utilizing recordings from trans-telephonic monitors (TTMs) and Holter monitoring. Using an endpoint of AA

burden, assessed by the greater amount of burden from Holter monitoring or TTMs, findings showed that 87% of the PAF and 82% of the PsAF patients demonstrated a post-ablation burden of less than 10 percent. Further, zero burden was observed in 69% of the PAF and 62% of the PsAF cohort.

Quality of Life Findings

Patient improvement in quality of life was determined based on answers to the

AF Effect On Quality-Of-Life Questionnaire (AFEQT) at baseline and 12 months post ablation.

The analysis showed that AA burden did not have to be reduced to zero to result in QoL improvement. In PAF patients that underwent PFA, AA burden less than 10% was associated with meaningful improvement in QoL. PsAF patients that underwent PFA experienced QoL improvement regardless of burden level.

Healthcare Utilization Findings

The analysis evaluated the relationship between AA burden and AF-related HCU (repeat ablations, cardioversions, and ER visits/hospitalizations) that occurred following PFA treatment For both PAF and PerAF patients, repeat ablations and cardioversion significantly increased with increasing AA burden.

“Catheter ablation technology has been shown to reduce AA burden, and now we're proud to be at the forefront of the next evolution in catheter ablation by demonstrating how novel pulsed field ablation with PulseSelect can support an advancement in meaningful improvements in quality of life,” said Rebecca Seidel, president, Cardiac Ablation Solutions business, which is part of the Cardiovascular Portfolio at Medtronic.

About PULSED AF

The PULSED AF trial is a prospective, single arm, multi-center clinical trial that treated 300 patients (150 with paroxysmal AF and 150 with persistent AF). Patients were enrolled across 41 sites in nine countries with 67 operators throughout the United States, Canada, Europe, Australia, and Japan. Patients underwent pulmonary vein isolation using the PulseSelect PFA System and underwent rigorous arrhythmia monitoring, including assessments at three, six, and 12 months, and weekly symptomatic trans-telephonic monitoring. 96% (287) of patients completed the 12-month follow up.

The PulseSelect PFA system is a breakthrough ablation technology that uses pulsed electric fields to efficiently isolate the pulmonary veins for the treatment of patients with PAF or PsAF. The single-shot PulseSelect System delivers pulsed electric fields through an ablation catheter designed specifically to interrupt irregular electrical pathways in the heart that trigger AF. However, unlike traditional methods of ablation that heat (radiofrequency ablation) or cool (cryoablation) the atrial tissue, the PulseSelect System uses a non-thermal approach and preferentially targets heart tissue with the goal of avoiding unwanted injury to surrounding structures, a risk of current ablation technologies. Worldwide, the PulseSelect System is investigational and not approved for sale or distribution. For more information on PULSED AF, visit Medtronic.com/PFA.

[1]Terricabras M et al. *JAMA Netw* Open; 2020; 3:e2025473.

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.

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 our world. 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.

For more information, contact:

Allison Kyriagis
Director of Communications
Medtronic
+1-612-750-6061

Ryan Weispfenning
Vice President & Head of Investor Relations
Medtronic

https://news.medtronic.com/Medtronic-PulseSelect-Pulsed-Field-Ablation-System-Results-in-Low-Atrial-Arrhythmia-Burden-for-AFib-Patients