Medtronic News

Real-World Data Demonstrate Significant Reduction in Complications and Reinterventions with Medtronic Micra Leadless Pacemaker

Results Presented at ESC 2021 Show Micra TPS Compares Favorably to Traditional Pacemakers

DUBLIN, Aug. 27, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced new data from the Micra Coverage with Evidence Development (CED) Study, the largest evaluation of leadless pacemakers to date, which showed the Micra™ Transcatheter Pacing System (TPS) was associated with a 38% reduction in reinterventions and a 31% reduction in chronic complications at 2-years compared with traditional transvenous (TV-VVI) pacemakers. The data were presented virtually today in a late-breaking trials presentation at the European Society of Cardiology (ESC) Congress 2021.

"There is considerable evidence supporting the safety and efficacy of leadless pacemakers, but limited data evaluating their long-term outcomes compared to traditional pacemakers in a real-world setting," said Jonathan P. Piccini, M.D., associate professor of medicine and director of cardiac electrophysiology at Duke University Medical Center. "The results from this study further support the connection of a lower risk of complications with leadless pacing compared with traditional transvenous single chamber pacing. These data should help guide physicians as they determine the best pacing options for their patients."

The Micra CED study is a continuously enrolling, observational, cohort study evaluating claims-based complications, utilization and outcomes of Micra TPS in the U.S. Medicare fee-for-service population. It is the first study to use Centers for Medicare & Medicaid Services (CMS) administrative claims data to evaluate clinical outcomes of leadless pacing in the real-world setting and compare outcomes to a contemporaneous cohort of patients implanted with transvenous-VVI pacemakers.

The CED study used statistical adjustment to account for differences in patient characteristics at baseline. Although Micra patients had more co-morbidities than transvenous VVI patients, the adjusted results showed patients with Micra had significantly fewer reinterventions compared to patients with TV-VVI devices (Micra 3.1% vs. TV-VVI 4.9%; adj. P=0.003) including significantly fewer system revisions, device removals, and upgrades to cardiac resynchronization therapy. Micra TPS patients also had significantly fewer chronic complications at 2-years (Micra 4.6% vs TV-VVI 6.5%; adj. HR 0.69, 95% CI: 0.60-0.81, P<0.0001). Although Micra patients had more comorbidities than transvenous-VVI patients, there was no difference in adjusted all-cause mortality at 2-years compared to the transvenous comparator population (adj. HR 0.97, 95% CI 0.91-1.04, P=0.37).

Researchers evaluated 6,219 patients implanted with Micra VR TPS and 10,212 patients implanted with traditional TV-VVI pacemakers; they compared system reinterventions, chronic complications, and all-cause mortality at 2-years after implant. Overall, patients implanted with Micra TPS were sicker (with a greater comorbidity burden) than TV-VVI patients, with higher rates of end stage renal disease (ESRD) (12.0% vs. 2.3%) and renal dysfunction (48.8% vs. 42.1%), and a higher Charlson Comorbidity Index score (5.1 vs. 4.6).

"As part of our commitment to improving outcomes for patients needing pacing therapy, we embraced the opportunity to evaluate our devices in a real-world setting," said Rob Kowal, M.D., Ph.D., chief medical officer of the Cardiac Rhythm Management business, which is part of the Cardiovascular Portfolio at Medtronic. "The results presented at ESC further reinforce the significant advantages of leadless pacemakers and support earlier findings that show a reduced risk of complications with Micra TPS. These data should assist physicians and patients to select the most appropriate, individualized pacing option to meet their goals."

Micra TPS is the only leadless pacing system available globally. Recently, Medtronic announced that more than 100,000

patients have received a Micra device worldwide.

About the Micra Transcatheter Pacing System (TPS)

Micra TPS is a leadless pacemaker option for patients who only require pacing in the right ventricle. Comparable in size to a large vitamin, Micra is less than one-tenth the size of traditional pacemakers yet delivers advanced pacing technology to patients via a minimally invasive approach. During the implant procedure, the device is attached to the heart with small tines and delivers electrical impulses that pace the heart through an electrode at the end of the device.

Unlike traditional pacemakers, Micra does not require leads or a surgical "pocket" under the skin, so potential sources of complications related to leads and pockets are eliminated - as are any visible signs of the device.

Micra received CE Mark in 2015 and was approved by the FDA in 2016.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. Medtronic strives to offer products and services of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies – alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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.

Contacts:

Ryan Mathre	Ryan Weispfenning
Public Relations	Investor Relations
+1-651-335-2338	+1-763-505-4626

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