Medtronic News

Procedure-Related Techniques and Care Pathways from the OPTIMIZE PRO Clinical Study Show Promising Early Outcomes for Patients Implanted with the Medtronic Evolut™ TAVR System

DUBLIN, April 28, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced results from an interim analysis of the first 171 patients (including 71 roll-ins) treated in the OPTIMIZE PRO clinical study. The post-market, prospective, multi-center study is evaluating procedural outcomes (including pacemaker rate) associated with procedure-related techniques and post-procedure TAVR care pathways when using the self-expanding, supra-annular Evolut™ PRO and PRO+ TAVR systems in patients with symptomatic severe aortic stenosis. The interim data was presented virtually at the Society for Cardiovascular Angiography and Interventions (SCAI) 2021 Scientific Sessions.

Study investigators utilized several procedural approaches with the Evolut TAVR system in the study, including the "cusp overlap technique," which is designed to help implanters assess and achieve the target implant depth in an effort to reduce interaction with the conduction system.

At 30 days, excellent safety outcomes were observed with zero death or disabling stroke and a low pacemaker rate (8.8%). Additionally, the Evolut platform showed excellent hemodynamic (blood flow) performance with low mean gradients (8.1 mm Hg) and low rates of residual total aortic regurgitation with the majority of subjects having none/trace (80.4%), and the rest mild (19.6%) at discharge. Patients also experienced an expedited discharge with a median hospital length of stay of one day.

The OPTIMIZE PRO study utilizes a TAVR care pathway to evaluate common practices and shared experiences such as conscious sedation and early mobilization. A conduction disturbance pathway evaluates efficiencies and heart team considerations for monitoring and managing patients with conduction disturbance who might be considered for a pacemaker post TAVR.

"The evolution of TAVR requires that we refine aspects of the procedure and post-procedure care pathways to improve patient outcomes," said Kendra Grubb, M.D., surgical director of the Structural Heart and Valve Center at Emory Healthcare in Atlanta, and co-principal investigator in the OPTIMIZE PRO study who presented the data at the meeting. "Interim results from this study demonstrate improvements, like low pacemaker rates and next-day discharge, and are supportive of the hypothesis that the cusp overlap technique can improve patient care."

The OPTIMIZE PRO study is being conducted at 46 study sites in the U.S. and Canada and up to 15 sites in Europe. The primary endpoint includes the rate of all-cause mortality or all-stroke at 30 days with secondary endpoints of discharge time, percent of patients with more than moderate aortic regurgitation, and the rate of pacemaker implant for new-onset or worsening conduction disturbance at 30 days. The study will also evaluate rehospitalization rates and discharge time at 30 days and one year.

"As a leader in transcatheter valves therapies, we are committed to helping implanting centers standardize and further refine their TAVR care pathways to improve patient outcomes," said Nina Goodheart, president of the Structural Heart & Aortic business, which is part of the Cardiovascular Portfolio at Medtronic. "In addition to helping us better understand the site-driven dynamics around conduction disturbance post-TAVR, the study also allows us to generate additional evidence around the Evolut PRO and PRO+ system's advanced sealing skirt and its impact on paravalvular leak."

The Evolut TAVR platform, including the Evolut™ R, Evolut™ PRO and Evolut PRO+ TAVR System, is indicated for symptomatic severe aortic stenosis patients across all risk categories (extreme, high, intermediate and low) in the U.S. The Evolut PRO and PRO+ valves feature an outer tissue wrap that adds surface area contact between the valve and the native aortic annulus to further advance valve sealing.

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. The company strives to offer products and services 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.

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