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# SCAI 2024: Medtronic transcatheter therapies show excellent outcomes in the treatment of congenital heart disease and severe aortic stenosis

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Medtronic, the global leader in healthcare technology, today announced the release of important clinical outcomes in two leading transcatheter valve therapies. The results for these studies were presented at the Society for Cardiovascular Angiography & Interventions (SCAI) 2024 Scientific Sessions in Long Beach, CA.

"The data presented at SCAI 2024 reinforces our commitment to providing solutions for structural heart patients with varying and complex anatomies," said Nina Goodheart, senior vice president and president, Structural Heart & Aortic, which is part of the Cardiovascular Portfolio at Medtronic. "We are seeing positive outcomes for patient groups in need of minimally invasive solutions – including meaningful insights into the benefits of the Harmony™ TPV system and additional evidence from the recently released SMART Trial and Optimize PRO addendum study that reinforce the Evolut™ TAVR system's performance in patients with severe aortic stenosis."

## TAVR Therapies

### Late-Breaking Clinical Science: SMART 1-Year Additional Data Outcomes

Medtronic also announced additional outcomes for the SMART Trial, specifically highlighting consistent findings between the two co-primary endpoints in patients <80 years or ≥80 years of age.

The SMART Trial was designed to better understand how the two most used transcatheter aortic valve replacement (TAVR) systems perform in patients with small aortic annuli (SAA), particularly in women who tend to have smaller heart valves compared to men. The study is an international, prospective, multi-center, randomized (1:1) post-market trial comparing the safety and performance of self-expanding versus balloon-expandable TAVR in patients with symptomatic severe aortic stenosis (AS) and SAA. The trial randomized and treated 716 patients, 87% of whom were women, across more than 80 sites worldwide. Eligible patients had a computed tomography aortic valve annulus area of ≤430 $mm^2$ and suitable anatomy for transfemoral TAVR with both an Evolut PRO/PRO+/FX and a SAPIEN 3™/3 Ultra™ valve.

"This analysis expands upon the data presented at the American College of Cardiology Annual Scientific Session last month, showing us that, no matter their age, treatment with the Evolut TAVR system provides optimal valve performance in small annulus patients," said Howard C. Herrmann, M.D., Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Penn., and lead investigator of the SMART Trial. "This study will be beneficial in helping clinicians apply tailored approaches to treatment and address the unique presentation of AS in the small annulus."

**Featured Abstract: Optimize PRO FX Addendum Study**

Data on 151 patients from the Optimize PRO FX addendum study were released in an oral abstract presentation session by Dr. Hemal Gada on Thursday. The study evaluated valve performance and procedural outcomes in patients who underwent TAVR with the Evolut FX TAV system, using an "optimized" TAVR care pathway and the cusp overlap technique. At 30 days, the rate of all-cause mortality or all stroke was 2.7% (all-cause mortality, 1.3%), and new permanent pacemaker implantation (PPI) was 6.7%. Median length of stay in the hospital was 1 day. Upon discharge from the hospital, 91% of patients had none or trace aortic regurgitation (AR), with the remainder (9%) having mild regurgitation – no patients had more than mild regurgitation. The Optimize PRO FX study is a post-market, multicenter prospective study conducted at 11 sites in the United States. Previous results from the Optimize PRO study interim analysis on 400 patients demonstrated favorable outcomes using an optimized TAVR care pathway and cusp overlap technique, which also resulted in low rates of new permanent pacemakers and no moderate or severe AR at 30 days[1].

"Like other recent evidence shows, the FX addendum to the Optimize PRO study reveals favorable clinical and hemodynamic outcomes with Evolut TAVR," said Hemal Gada, M.D., president of the UPMC Heart and Vascular Institute and medical director of the Structural Heart Program at UPMC. "The use of standardized optimized care pathways and cusp overlap technique with the Evolut FX TAV system is associated with low PPI rates and no moderate or severe AR at 30 days, a finding consistent with other recently released clinical evidence, including from the SMART Trial, about the Evolut TAVR system."

**Congenital Therapies**

**Featured Abstract: Harmony TPV Midterm Outcomes Data**

Earlier today, the mid-term results from an expanded cohort of Harmony transcatheter pulmonary patients were presented at SCAI 2024. The results show an excellent safety profile, with no new deaths, thrombosis, major stent fracture, or arrhythmia between 2 and 3 years of follow-up. The data demonstrates sustained valve function with no more than mild pulmonary regurgitation (PR) in all but one patient at 3 years. Positive effects on right ventricular (RV) remodeling were observed with improved RV stroke volume and RV end-diastolic volume through two years.

"Harmony TPV continues to perform well, with positive impacts on remodeling of the heart, quality of life, and functional outcomes. We were reassured in seeing no new arrhythmia in follow-up. We will continue to track midterm and long-term outcomes associated with valve performance and longevity," said Brian Morray, M.D., Division of Pediatric Cardiology, Seattle Children's Hospital, Seattle, WA, and principal investigator.

The Harmony TPV system was designed to treat patients with right ventricular outflow tract (RVOT) anomalies in native or surgically repaired patients with severe pulmonary valve regurgitation, a condition where blood leaks

back into the right lower chamber of the heart after being pumped into the lungs. The Harmony TPV provides these patients with a minimally invasive treatment alternative.

The study evaluated an expanded cohort of Harmony TPV clinical trial participants from the Harmony Native Outflow Tract Early Feasibility Study (EFS), Harmony TPV Pivotal Trial, and Continued Access Study (CAS). Eligible patients had severe PR by echocardiography or PR fraction ≥30% by cardiac magnetic resonance imaging and a clinical indication for surgical pulmonary valve replacement. In the study, 86 patients were implanted with a commercially available Harmony valve, all of whom remained implanted for more than 24 hours.

**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 95,000+ 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 LinkedIn.

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[1] Grubb, et al. J Am Coll Cardiol Intv 2023;16:558–570

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