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New late-breaking data from Medtronic Evolut™ Low Risk Trial demonstrate strong clinical and cost-effectiveness benefits of TAVR platform

CRT 2024: Evolut TAVR is a safe, effective, and economically cost-effective treatment option for low-risk severe aortic stenosis patients compared to surgery up to four years

Medtronic plc, a global leader in healthcare technology, today announced two late-breaking data presentations on four-year outcomes from the Evolut™ Low Risk Trial. A cost-effectiveness analysis demonstrates the positive economic value of transcatheter aortic valve replacement (TAVR) using Evolut TAVR compared to surgical aortic valve replacement (SAVR) for low-risk patients. In addition, contemporary data from the Evolut Low Risk Trial reinforces the robust long-term clinical outcomes of Evolut TAVR compared to SAVR in low-risk patients. The findings were presented as late-breaking clinical trials at the Cardiovascular Research Technologies (CRT) 2024 Conference.

The Medtronic Evolut TAVR platform includes devices less invasive than traditional open-heart surgery for the treatment of symptomatic severe aortic stenosis.

"At Medtronic, we continue to emphasize that valve design matters. These data further exemplify Medtronic's dedication to providing differentiated treatment options like the Evolut TAVR platform to reach the growing population of low-risk symptomatic severe aortic stenosis patients," said Nina Goodheart, Senior Vice President and President, Structural Heart & Aortic, which is part of the Cardiovascular Portfolio at Medtronic. "We are proud of the excellent clinical outcomes and sustained valve performance[1,2], effectiveness, and economic benefits of Evolut TAVR and are committed to advancing evidence around the long-term clinical and economic patient benefits."

Evolut Low Risk Trial: Cost-Effectiveness Analysis

Evolut Low Risk Trial four-year data were analyzed to determine cost-effectiveness results of TAVR versus SAVR across the spectrum of surgical mortality risk. The findings showed a strong economic benefit of Evolut TAVR for low-risk patients from a U.S. healthcare system perspective.

The results demonstrate Evolut TAVR resulted in a lifetime incremental cost-effectiveness ratio (ICER) of $2,119 per quality-adjusted life year (QALY) gained, which is consistent with high economic value.[3] At 30 days, the estimated cost (including index procedure, hospitalization, and rehabilitation) was $5,189 lower with TAVR compared with SAVR ($45,887 versus $51,075, respectively). Within the US healthcare system, current ACC/AHA guidelines consider an ICER <$50,000 per QALY gained to indicate "high value" while an ICER between $50,000 and $150,000 per QALY gained is considered "intermediate value" 2022 Medicare data was used to obtain contemporary cost estimates for TAVR and SAVR index hospitalization along with key cost drivers.

"As more and more patients are diagnosed with aortic stenosis and undergo TAVR, it is important to use devices that offer exceptional results for patients, while also delivering economic value to the healthcare system. These data complement the extensive body of clinical evidence for Evolut TAVR and demonstrate that it is a solution that provides substantial benefit to our patients in a highly cost-effective manner," said David J. Cohen, MD, MSc, Director of Clinical and Outcomes Research at the Cardiovascular Research Foundation, Director of Academic Affairs at St. Francis Hospital, and faculty member at Columbia University.

4-Year Outcomes: SAVR with Contemporary Valves Versus Self-Expanding TAVR Outcomes

Findings from the Evolut Low Risk Trial four-year data comparing TAVR versus SAVR in patients with severe aortic stenosis were re-evaluated with the exclusion of Trifecta surgical valves that were previously withdrawn from the market due to durability concerns. This analysis included the evaluation of 1,292 attempted implants in patients who were randomized to TAVR with a self-expanding, supra-annular CoreValve/Evolut R/PRO valve or to SAVR.

In this contemporary analysis, all-cause mortality or disabling stroke rates at four years were 10.7% in the Evolut TAVR cohort compared to 14.2% in the SAVR cohort (p=0.06). Evolut TAVR had significantly better hemodynamics, an indicator of valve durability, compared to SAVR using contemporary valves (mean gradient 9.8 mmHg TAVR; 11.8 mmHg SAVR; p<0.001) at four years.

"The Evolut TAVR System continues to demonstrate positive clinical outcomes compared to SAVR. This new data supports the growing body of evidence for TAVR at a time when aortic stenosis is the most common surgically managed heart valve disease," said Basel Ramlawi, MD, System Chief of Cardiothoracic Surgery at Main Line Health System and Co-Director of the Lankenau Heart Institute. "We are encouraged by the results of this contemporary data, showing that we can help improve outcomes in patients with less risk of mortality and disabling stroke compared to the surgical option."

About the Evolut Low Risk Trial

The Evolut Low Risk Trial was a prospective, randomized, multicenter, noninferiority study to assess the safety and efficacy of the Evolut TAVR System compared to SAVR in low-risk patients. Low-risk patients, defined as having a low predictive risk of 30-day surgical mortality were randomized to TAVR with a Medtronic self-expanding, supra-annular Evolut R, PRO, or CoreValve™ bioprosthesis versus SAVR. A total of 1,414 patients underwent attempted implant (730 TAVR; 684 SAVR).

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.

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] Forrest JK, et al. 4-Year Outcomes of Patients With Aortic Stenosis in the Evolut Low Risk Trial. J Am Coll Cardiol. 2023 Nov 28;82(22):2163-2165.

[2] O'Hair D, Yakubov SJ, Grubb KJ, et al. Structural valve deterioration after self-expanding transcatheter or surgical aortic valve implantation in patients at intermediate or high risk. JAMA Cardiology. 2023;8(2):111. doi:10.1001/jamacardio.2022.4627

[3] QALY is a measurement of the quantity and quality of life.

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