Medtronic News

Medtronic Evolut™ TAVR platform outperforms surgery with sustained valve performance for low-risk patients at four years

TCT 2023: Medtronic adds to the body of evidence for Evolut TAVR with late-breaking clinical trial data from the Evolut Low Risk Trial

DUBLIN and SAN FRANCISCO, Oct. 24, 2023 /PRNewswire/ -- Medtronic plc (NYSE:MDT), a global leader in healthcare technology, today announced four-year results from the Evolut Low Risk Trial. The Medtronic Evolut™ transcatheter aortic valve replacement (TAVR) system demonstrated exceptional outcomes and sustained valve performance, proven by significantly better hemodynamics than surgical aortic valve replacement (SAVR). Only Evolut TAVR has reported consistently lower and diverging rates of death or disabling stroke versus state-of-the-art surgery, at four years. The data were presented at the 35th Transcatheter Cardiovascular Therapeutics (TCT) conference, the annual scientific symposium of the Cardiovascular Research Foundation and simultaneously published in the *Journal of the American College of Cardiology*.

Since the approval of TAVR in low-risk surgical patients, there is an ongoing need for evidence to better understand the intermediate and longer-term durability of TAVR devices of different designs.

"As we see patients in the Evolut Low Risk trial continue to show positive outcomes and sustained valve performance compared to surgery out to four years, this helps us establish intermediate-term evidence for Evolut TAVR and helps define what this might look like in the long term," said Dr. Michael Reardon, Allison Family Distinguished Chair of Cardiovascular Research and professor of cardiothoracic surgery at the Houston Methodist Hospital and principal investigator of the trial. "These results are not only encouraging, but pivotal in shaping treatment decisions for low-risk patients with symptomatic severe aortic stenosis. We are seeing sustained, excellent valve performance in patients treated with Evolut TAVR, which ultimately translates into improved outcomes, including mortality and disabling stroke.[1] This intermediate-term result underscores the belief that valve design matters, and previously published data points to superior outcomes* and better design in the Evolut TAVR platform."

The Evolut™ Low Risk Trial was a prospective, randomized, multicenter, international, noninferiority study to assess the safety and efficacy of the Evolut TAVR system compared to surgical aortic valve replacement (SAVR) in low-risk patients. Low-risk patients, defined in the trial as having a predicted risk of 30-day mortality <3% per multidisciplinary local heart team assessment, were randomized to TAVR with a Medtronic self-expanding, supra-annular Evolut R, PRO, or CoreValve™ bioprosthesis vs. SAVR. A total of 1,414 patients underwent attempted implant (730 TAVR; 684 SAVR).

The study showed continued favorable outcomes for Evolut TAVR compared to SAVR at four years for the primary endpoint of all-cause mortality or disabling stroke. At four years, a 26% relative reduction in the hazard (p= 0.05) of death or disabling stroke with TAVR (10.7%) was seen compared to SAVR (14.1%). The absolute difference between treatment arms for the primary endpoint continued to increase over time, representing a clinical benefit from Evolut TAVR for patients at four years compared to surgery. The findings also showed the composite of all-cause mortality, disabling stroke, or aortic valve rehospitalization was 18.0% with TAVR and 22.4% with SAVR (p=0.04).

"The Medtronic Low Risk data presented today at TCT demonstrates our continued commitment to generating evidence on our Evolut TAVR platform and providing treatment options for low-risk symptomatic severe aortic stenosis patients, a growing patient population," said Nina Goodheart, senior vice president and president of the Structural Heart & Aortic business within the Cardiovascular Portfolio at Medtronic. "We are dedicated to supporting advanced, lifelong patient care by empowering physicians with the latest minimally invasive, clinically proven technology to best treat their patients."

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered inDublin, 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 more than 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.

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] 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

* Versus surgery in high-risk patients on mortality at 1 year[2] and vs surgery in low-risk patients on MPG and EOA at 1 year and KCCQ at 30 days[3]

[2]Adams DA, et al. N Eng J Med. 2014;370:1790–1798.

[3] Popma JJ, et al. N Engl J Med. 2019;380:1706–1715.

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