SEP 18, 2022

MEDTRONIC UNVEILS NEW DATA FROM INVESTIGATIONAL INTREPID™ TRANSCATHETER MITRAL VALVE REPLACEMENT PROGRAM TO EXPAND TREATMENT OPTIONS FOR SEVERE MITRAL REGURGITATION

TCT 2022: Late-breaking data from Intrepid™ Pilot Study 3-year follow-up & 1-year follow-up from Transfemoral EFS study demonstrate promising valve performance Medtronic today announced new data...

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Medtronic today announced new data of the Intrepid transcatheter mitral valve replacement (TMVR) system, including late-breaking results from the Intrepid™ TMVR Pilot Study and Intermediate-Term Outcomes of the Intrepid TMVR Transseptal Early Feasibility Study (EFS) at the 34th Transcatheter Cardiovascular Therapeutics (TCT) conference, the annual scientific symposium of the Cardiovascular Research Foundation. The data offers new clinical insights supporting the Medtronic Intrepid TMVR System for the treatment of mitral regurgitation (MR).

MR occurs when blood flows backward through the mitral valve and into the atrium each time the left ventricle contracts. If left untreated, MR can lead to heart failure or death. Due to the complexity of the mitral valve anatomic structure and multiple comorbidities typically present in such patients, limited medical therapies are available to clinicians and their patients.

Late-Breaking Clinical Science: Intrepid TMVR Pilot Study Mid-Term Echocardiographic Outcomes

Presented as Late-Breaking Clinical Science, results from the Intrepid Pilot Study provide the longest follow-up from the largest series of high surgical risk patients with severe, symptomatic MR treated with a transapical TMVR system. The study assessed feasibility of treating MR with the investigational Intrepid Transapical Transcatheter Mitral Valve Replacement (TMVR) System. A transapical approach utilizes a small incision in the chest to insert the delivery system and perform mitral valve replacement.

Results from the prospective, multi-center, non-randomized Intrepid Pilot study demonstrated promising valve performance. At three years, echocardiographic outcomes showed stable valve function with persistent MR reduction in nearly all patients, low mean mitral valve gradients, and significant reduction in left ventricular end diastolic volume.

"The data presented at TCT adds to the growing body of evidence demonstrating the Intrepid TMVR System is a promising long-term solution for patients with severe, symptomatic MR, who are at high risk for conventional mitral valve surgery," said Renuka Jain, M.D., cardiologist with Aurora St. Luke's Medical Center and investigator in the Intrepid Pilot Study.

Innovation Session: Intrepid TMVR Transseptal Early Feasibility Study Intermediate-Term Outcomes
Medtronic announced Intermediate-Term Outcomes of the Intrepid Early Feasibility Study (EFS) of its minimally invasive Intrepid Transfemoral Transcatheter Mitral Valve Replacement (TMVR) System to treat MR. Findings of the prospective, multicenter, non-randomized EFS were presented as part of the Mitral Innovation Session at TCT.

The analysis includes 30-day outcomes in 30 patients from the Intrepid EFS and the one-year results for the first 14 patients, demonstrating successful device implantation and valve performance. Results include:

- No mortality at 30 days and 1 year.
- No stroke at 30 days and 1 year.
- High rates of device and procedural success
- Strong valve performance including near complete elimination of MR in all patients (91% with none/trace MR at 1 year)
- Improved symptoms and QoL (100% in NYHA class I/II at 1 year)

"We are encouraged by these early results for the Intrepid TMVR system using the novel transfemoral system and look forward to furthering evidence around the outcomes of the device," said Firas Zahr, M.D., interventional cardiologist and co-director of the Complex Heart Valve Program at Oregon Health & Science University and principal investigator.

The Intrepid TMVR system is available for investigational use only and it is not approved anywhere for use outside of clinical studies. As part of its commitment to developing solutions for the treatment of valve disease, Medtronic is sponsoring and currently enrolling participants to the landmark APOLLO Trial. APOLLO is designed to evaluate the safety and efficacy of the Intrepid system in patients with severe symptomatic mitral regurgitation.[1]

"With the Intrepid TMVR system, our goal is to create a safe and effective therapy for the large proportion of patients who are considered ineligible for surgical mitral valve replacement," said Nina Goodheart, Senior Vice President and President, Structural Heart & Aortic, which is part of the Cardiovascular Portfolio at Medtronic. "The presentations at TCT build on the existing data on the Intrepid TMVR system and are another step forward in our mission to provide new options for patients with mitral valve disease."

The Intrepid TMVR system integrates self-expanding, dual-stent technology with a tissue valve that is delivered through a catheter and placed directly into the native mitral valve to restore normal blood flow through the heart without the need for open-heart surgery. Using a delivery catheter to insert the valve into the heart, the replacement valve is expanded directly into the malfunctioning mitral valve. The outer stent frame is designed to

anchor and conform to the native valve without the need for additional sutures, tethers, or attachments to secure the prosthesis. The inner stent houses the valve, which is made from bovine tissue and is intended to maintain blood flow.

[1]https://clinicaltrials.gov/ct2/show/NCT03242642

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