

LATE-BREAKING DATA ON ABBOTT'S MITRACLIP® SYSTEM SHOW CONTINUED BENEFIT FOR PEOPLE WITH MITRAL REGURGITATION, MOST COMMON HEART VALVE DISEASE

- 92.8% procedural success observed in reducing leaky heart valve
- 80.0% of those treated free from repeat heart failure re-hospitalization
- 85.9% of patients were discharged to home after two-day average hospital stay

WASHINGTON, March 18, 2017 /PRNewswire/ -- Abbott (NYSE: ABT) today announced favorable one-year outcomes from the largest study of real-world experience for the MitraClip system in transcatheter mitral valve repair (TMVR) procedures in the United States. MitraClip treats people with degenerative mitral regurgitation (DMR, also known as leaky heart valve), a serious condition involving a dysfunction of the heart's mitral valve, which regulates blood flow into the heart's main pumping chamber.

The study analyzed data from the Transcatheter Valve Therapy (TVT) registry involving nearly 3,000 DMR patients who were high-risk for surgery. Following minimally invasive implantation with MitraClip, patients had significant improvements, including 92.8 percent of patients achieving post-procedural mitral regurgitation (MR) severity grade of less than or equal to 2 (acute procedural success defined as $MR \leq 2$). In addition, 80.0 percent of MitraClip patients remained free from heart failure (HF) re-hospitalization in the year after implantation. Most patients—85.9 percent of people treated—were discharged to their homes after an average hospital stay of only two days. The average age of patients was 82.

The data were presented by Paul Sorajja, M.D., director of the Center of Valve and Structural Heart Disease at Minneapolis Heart Institute, cardiologist at Abbott Northwestern Hospital in Minneapolis and principal investigator of the study, during a late-breaking featured clinical research session of the American College of Cardiology's (ACC) 66th Annual Scientific Session.

"The consistent one-year results seen in this study validate that treatment with MitraClip can provide meaningful reduction in the severity of mitral regurgitation," said Dr. Sorajja. "The consistency of data over time in this large patient registry underscore the valuable impact MitraClip has on the overall health of very sick people living with this silent killer."

Mitral regurgitation is a debilitating, progressive and life-threatening disease in which the leaflets of the mitral valve do not close completely, causing blood to flow backward and leak into the left atrium of the heart during the cardiac cycle. The condition can raise the risk of irregular heartbeats, stroke, and heart failure, which can be deadly.

Nearly one in ten people over the age of 75 have moderate to severe MR¹, which is frequently difficult to diagnose. Patients often may not be eligible for the standard-of-care surgery because of advanced age, frailty, multiple comorbidities or other complicating factors. Until the regulatory approval of MitraClip, these high surgical risk patients could only manage their symptoms, such as shortness of breath and fatigue, with medications that did not stop the progression of the disease.

"Abbott's goal is to improve health, and our MitraClip therapy provides a much-needed solution for gravely ill people who have very few options," said Michael Dale, general manager of Abbott's structural heart business. "The consistency in data across multiple trials reinforce the nearly immediate impact that MitraClip has on people's quality of life, allowing them to lead fuller, longer lives."

About the Transcatheter Valve Therapy (TVT) Registry

The STS/ACC TVT Registry™ is a benchmarking tool developed to track patient safety and real-world outcomes related to transcatheter valve replacement and repair procedures and emerging treatments for valve disease patients. Created by The Society of Thoracic Surgeons (STS) and the American College of Cardiology, the TVT Registry is designed to monitor the safety and efficacy of these new technologies for the treatment of valve disease. Through the capture and reporting of patient demographics, procedure details, and facility and physician information, the TVT Registry provides a data repository capable of delivering insight into clinical practice patterns and patient outcomes.

About MitraClip

The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation ($MR \geq 3+$) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation. The [MitraClip System](#) is available in the United States and in more than 50 countries around the world. More information, including important safety information, can be found at

http://www.abbottvascular.com/docs/ifu/structural_heart/eIFU_MitraClip.pdf

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¹ Nkomo VT, Gardin JM, Skelton TN, Gottdiener JS, Scott CG, Enriquez-Sarano M. Burden of valvular heart diseases: a population-based study. Lancet. 2006 Sep 16;368(9540):1005-11.
<https://www.ncbi.nlm.nih.gov/pubmed/16980116>

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