

# Abbott's MitraClip® System Shown To Mend Hearts And Improve Lives In People In The United States

- Favorable late-breaking clinical trial data from initial commercial use presented on transcatheter mitral valve repair system at ACC 2015

SAN DIEGO, March 15, 2015 [/PRNewswire/](#) -- About three years ago, Betty Vaughn of Golden Valley, Minn., started to feel light-headed, fatigued and out of breath when she walked up and down the stairs. After visiting her doctor, the 89-year-old was diagnosed with degenerative mitral regurgitation (DMR), a heart condition 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. After her diagnosis, Paul Sorajja, M.D., cardiologist at Abbott Northwestern Hospital in Minneapolis, performed a transcatheter mitral valve repair (TMVR) procedure on Vaughn, who was not a good candidate for surgery, using Abbott's (NYSE: ABT) MitraClip® in October 2014. Now, just months after the procedure, Vaughn has resumed many of the activities she loves, like working in the yard and playing cards with friends.

Vaughn's story shows how MitraClip can help people with a leaky heart valve feel better and resume their active lives. It's one example of the favorable outcomes from the initial commercial experience of transcatheter mitral valve repair with MitraClip in the United States, which were presented today during the late-breaking clinical trial session at the American College of Cardiology's (ACC) 64<sup>th</sup> Annual Scientific Session & Expo.

Abbott's MitraClip treats people with DMR, which is a condition involving a dysfunction of the heart's mitral valve. It is a treatment option for people who are not good candidates for surgery, the current standard of care, because of their advanced age, frailty or other complicating factors. In the United States, mitral regurgitation (MR) is the most common valve disease, affecting nearly one in 10 people age 75 and older. People with MR often have difficulty with everyday activities, such as climbing stairs, and may require long periods of rest due to fatigue.

In the study, a transcatheter valve therapy (TVT) registry formed from a partnership with the Society of Thoracic Surgeons (STS) and ACC, researchers evaluated data from 564 people with TMVR who were treated with MitraClip following FDA approval of the device in October 2013 through August 2014. The data continue to support the use of MitraClip, with successful treatment for 93 percent of people in the study. The treated group's median age was 83 years-old, and they were not candidates for surgery because they were too frail or had other complicating factors. Dr. Sorajja, the lead investigator for this study, shared the data at today's ACC session.

"The results of this MitraClip study are very favorable and consistent with the results we saw in studies prior to the therapy's U.S. approval," Dr. Sorajja said. "The results show clinically meaningful reduction in the severity of mitral regurgitation and improvement in the overall health of very sick people with prohibitive risk DMR who have no other meaningful options to improve their lives."

In the ACC presentation, Dr. Sorajja concluded that treatment with MitraClip for prohibitive risk patients with symptomatic MR is durable in a real-world commercial setting. Key findings from the 564 patients treated with the MitraClip device demonstrated the following:

- Prior to treatment, more than 90 percent of patients had a mitral regurgitation grade of 3 or 4, indicating significant leakage of the mitral valve. After treatment with MitraClip, 93 percent of patients achieved an MR grade of less than or equal to 2, with 63.6 percent at a grade of less than or equal to 1, demonstrating a significant decrease in leakage.
- Average length of stay in the hospital was 3 days, with 82 percent discharged home.
- Adverse events and procedural complications were low, consistent with clinical trial experience.

Vaughn knows what it feels like to suffer from MR. After receiving a MitraClip, however, her life has been improved.

"[My doctor] said I would feel better, and I did," Vaughn said. "That's the difference. I'm living now. I'm doing much better."

To learn more about mitral regurgitation [click here](#) for an infographic. For more information about MitraClip visit [www.mitraclip.com](http://www.mitraclip.com).

## About Mitral Regurgitation

Mitral regurgitation is a debilitating, progressive and life-threatening disease in which a leaky mitral valve causes a backward flow of blood in the heart. The condition can raise the risk of irregular heartbeats, stroke, and heart failure, which can be deadly.

Mitral regurgitation is common, affecting more than 4 million Americans – nearly one in 10 people aged 75 and above.<sup>1</sup> Open heart mitral valve surgery is the standard-of-care treatment, but many people are at prohibitive risk for an invasive procedure. Medications for the condition are limited to symptom management and do not stop the progression of the disease.

## 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 (ACC), 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 the MitraClip Device**

Abbott's MitraClip repairs the mitral valve without the need for an invasive surgical procedure. The device is delivered to the heart through the femoral vein, a blood vessel in the leg, and once implanted, allows the heart to pump blood more efficiently, thereby relieving symptoms and improving people's quality of life. People undergoing MitraClip treatment typically experience short recovery times and short hospital stays of two to three days.<sup>ii</sup> More than 20,000 people around the world have been treated with the MitraClip device.

For more information, including important safety information, please visit [www.mitraclip.com](http://www.mitraclip.com).

### **About Abbott:**

Abbott is a global healthcare company devoted to improving life through the development of products and technologies that span the breadth of healthcare. With a portfolio of leading, science-based offerings in diagnostics, medical devices, nutritionals and branded generic pharmaceuticals, Abbott serves people in more than 150 countries and employs approximately 73,000 people.

Visit Abbott at [www.abbott.com](http://www.abbott.com) and connect with us on Twitter at @AbbottNews.

<sup>i</sup> 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. <http://www.ncbi.nlm.nih.gov/pubmed/16980116>


<sup>ii</sup> Data on file at Abbott; Rogers, JH, Franzen, O. Percutaneous edge-to-edge MitraClip therapy in the management of mitral regurgitation. *European Heart Journal* (2011) 32, 2350–2357.

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