Henry Ford Health System

CARDIO BEAT

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New Watchman™ Implant Reduces Stroke Risk

Caused by Abnormal Heart Rhythm Without Blood Thinners

Cardiologists at Henry Ford Hospital have implanted a device that reduces the risk of stroke in patients with an irregular heartbeat, one of only a handful of hospitals in the Midwest offering this procedure; this adds another option to its arsenal of tools for certain patients with atrial fibrillation.

"This is a first in Detroit and first-ever commercial Watchman™ implant at a non-clinical trial site," says Cardiologist Claudio Schuger, M.D., Henry Ford section head of Cardiac Electrophysiology.

The Watchman™ Left Atrial Appendage Closure device, recently approved by the U.S. Food and Drug Administration, is designed for atrial fibrillation (AF) patients who cannot tolerate blood thinners long term due to increased risk of bleeding complications. The Watchman™ closes off the left atrial appendage, dramatically reducing the risk of stroke and alleviating the need for blood thinners.

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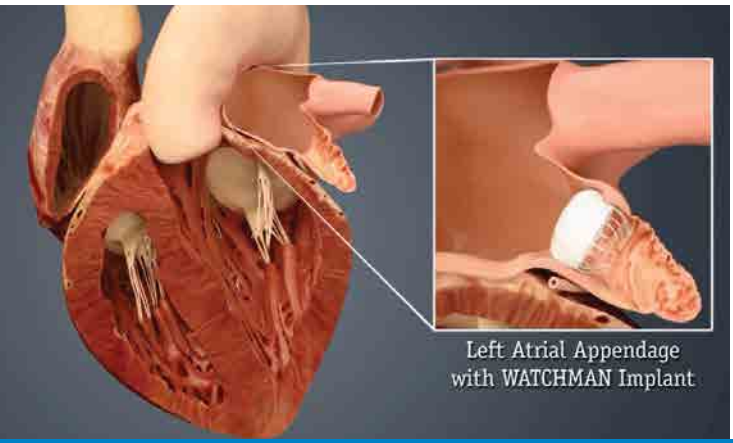
Implanting the Watchman™ device at Henry Ford Hospital in Detroit on April 16, 2015, are, from left, Boston Scientific Watchman™ Clinical Specialist Joe Whitaker; Proctor Cardiologist Vijay Swarup, M.D., of the Arizona Heart Rhythm Center in Phoenix; Henry Ford Section Head of Cardiac Electrophisiology Claudio Schuger, M.D., and Henry Ford Cardiologist Arfaat Khan, M.D.



INSIDE

New Watchman™ Implant Reduces Stroke Risk

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Implanting the Watchman™ device takes about one hour. A catheter is inserted through a leg vein and into the heart, where the Watchman™ device is opened to seal off the left atrial appendage sack. Following the procedure, patients typically need to stay in the hospital for 24 hours. Most patients will be able to discontinue the use of blood thinners after 45 days.

Claudio Schuger, M.D.
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William W. O'Neill, M.D.
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The Watchman™ device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

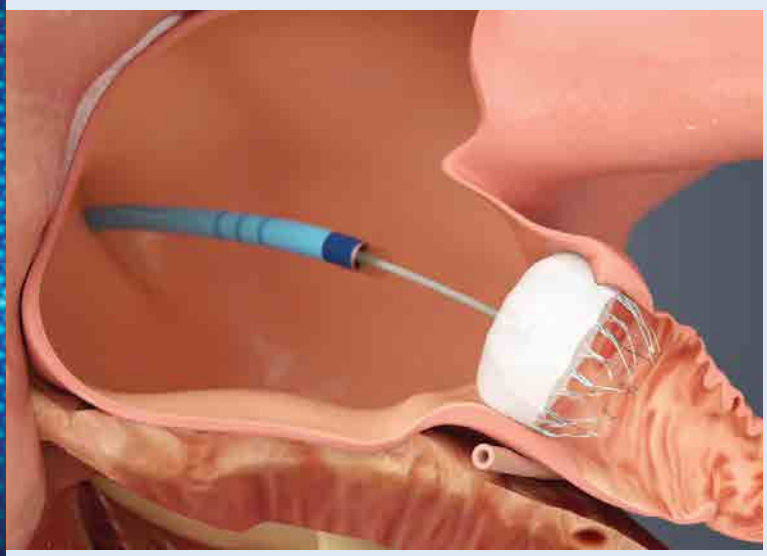
- Are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for warfarin;
- Have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.

As a result of this new procedure, there are only very rare cases that we cannot treat," says the Director of the Henry Ford Center for Structural Heart Disease, William W. O'Neill, M.D., an internationally recognized leader in the treatment of heart disease, who will also perform the procedure at Henry Ford Hospital.

The most common treatment to reduce stroke risk in patients with AF is blood thinners. Despite the proven efficacy, long-term use of blood thinners is not well-tolerated by some patients and carries a significant risk for bleeding complications. Researchers say nearly half of AF patients eligible for blood thinners are currently untreated due to tolerance and adherence issues.

The Watchman™ device, developed by Boston Scientific, is approved by medical boards in more than 70 countries and has been approved in Europe since 2005. Cardiologists have implanted the device in more than 10,000 patients around the world.

The procedure makes Henry Ford one of the few Midwest hospitals that offer both the Watchman™ and the LARIAT™ procedure options, each alternatives for those with atrial fibrillation who are at risk of stroke but who cannot tolerate blood thinners. In the LARIAT™ procedure, cardiologists cinch off the left atrial appendage instead of blocking it off with the Watchman™ device.



Watchman™ Device closes off left atrial appendage.

RESEARCH

Cardiology Studies Enrolling Patients

The following studies are being conducted:

THEMIS: In this study the long-term effects of the FDA approved drug BRILLINTA (ticagrelor) 90mg taken twice daily on the incidence of cardiovascular death, myocardial infarction or stoke in patients with Type 2 Diabetes Mellitus versus placebo for the prevention of major cardiovascular events is being studied.

ISCHEMIA: Sponsored by the National Heart, Lung and Blood Institute, the primary objective of this study is to determine whether an initial invasive (INV) strategy of cardiac catheterization and optimal revascularization is feasible, in addition to optimal medical therapy (OMT) in patients with stable ischemic heart disease and at least moderate ischemia on ischemia testing to reduce the incidence of the composite of cardiovascular death or nonfatal myocardial infarction compared with a conservative strategy of optimal medical therapy alone with cardiac catheterization and revascularization reserved for failure of OMT.

Primary Investigator, Khaled Nour, M.D.

To learn more about these studies or to enroll a patient, contact Blake Vostrirancky, MS, ACSM-RCEP, clinical research coordinator at (313) 492-0524

Electrophysiology Studies Underway

The following EP studies are being conducted:

CABANA is a Catheter Ablation versus Antiarrhythmic Drug Therapy for Atrial Fibrillation a multi-center prospective open label clinical trial, sponsored by Duke University.

ENHANCE CRT is a CRT implant strategy using the longest electrical delay for non-left bundle branch block patients. This is a prospective, randomized post market pilot study, sponsored by St. Jude.

RAID or Ranolazine ICD trial is being conducted to determine whether ranolazine administration will decrease the likelihood of a composite arrhythmia endpoint consisting of ventricular tachycardia or ventricular fibrillation (VT/VF) requiring antitachycardia pacing (ATP), ICD shocks, or death, sponsored by University of Rochester.

S-ICD PAS, structured as a post approval study of the S-ICD® System, it is sponsored by Boston Scientific.

Primary Investigator, Claudio Schuger, M.D.

To learn more or to enroll a patient, contact Karlee Sprader, EP research coordinator at (313) 916-3766.

Heart Failure Research in Progress

The following Heart Failure trials are available to patients:

INcrease Of VAgal TonE in chronic Heart Failure (INOVATE-HF) – is a randomized device trial to establish the Safety and Efficacy of CardioFit® for the Treatment of Subjects with Heart Failure and Left Ventricular Dysfunction.

PARAGON-HF is an outpatient oral drug trial for patients with preserved ejection fraction heart failure. This is a multicenter, randomized, double-blind, parallel group, active controlled study to evaluate the efficacy and safety of LCZ696 compared to valsartan, on morbidity and mortality in heart failure patients (NYHA Class II-IV) with preserved ejection fraction.

BAY 1021189 is a study of patients with worsening heart failure with preserved ejection fraction.

TRUE-HF- Phase III, is an inpatient trial for Acute Decompensated Heart Failure (ADHF). It is a multicenter, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of Ularitide (Urodilatin), an intravenous infusion in patients suffering from ADHF.

RELAX TRIAL, is a multicenter, randomized, double-blind, placebo-controlled phase III study to evaluate the efficacy, safety and tolerability of Serelaxin when added to standard therapy in acute heart failure patients.

To learn more about these studies or to enroll a patient, contact Karen Leszczynski, R.N., CCRC, clinical research coordinator at (313) 916-3502.

To connect with a Henry Ford physician, call:

Heart & Vascular Institute

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RESEARCH

ENDEAVOUR: A Study for Transthyretin Cardiac Amyloidosis

Amyloidosis is a systemic disease which can affect the heart and is an under-recognized cause of congestive heart failure. Until now, few options for treatment have been available for the hereditary form of amyloidosis called transthyretin cardiac amyloidosis, which can affect the heart and nerves.

This randomized study will look at the effects of a treatment drug – Revusiran versus placebo for TTR mutation cardiac amyloidosis. Patients will have a 2:1 chance of receiving Revusiran vs. placebo over 18 months. Revusiran is a small interfering RNA (siRNA) that targets the mutant TTR gene, essentially turning it off so that no TTR amyloid protein are produced.

Those admitted into the ENDEAVOUR study will first participate in the Discovery study. With a simple blood draw, patients are genetically tested for transthyretin (TTR) mutation that could lead to cardiac amyloidosis. Those testing positive for the TTR mutation will have further screening and then be considered for the ENDEAVOUR study.

Karthik Ananthasubramaniam, M.D

Those with the mutation will be additionally screened for an opportunity to participate in the ENDEAVOUR study, testing a RNA transcriptase inhibitor called revusiran (versus placebo) for treatment of the hereditary form of transthyretin amyloidosis. Patients will not qualify if they are diagnosed to have light chain amyloidosis.

For patients to participate, those suspected may have TTR cardiac amyloidosis or a prior diagnosis of TTR amyloidosis as a cause of heart failure may qualify for the study. Patients with AL amyloidosis are excluded.

Please contact Research Coordinator, Blake Vostrirancky, at (313) 492-0524 or Primary Investigator Karthik Ananthasubramaniam, M.D., director, Nuclear Cardiology and Echocardiography at (313) 916-4420 for further information.

Henry Ford Hospital *is the only site in Michigan* currently screening for a study of a potential treatment of transthyretin amyloidosis. Patients with heart failure and other specific characteristics of cardiac amyloidosis will be screened for a particular genetic mutation associated with transthyretin amyloidosis.