Stroke prevention is the most important aspect of managing the increasingly common problem of atrial fibrillation (AFib). To address this issue, cardiologists at Lourdes Health System are among the first in the area to provide the Watchman device to AFib patients who cannot take blood thinners. This fabric membrane on a small wire frame is implanted by catheter in the opening of the left atrial appendage (LAA) to prevent blood clots of harmful size from exiting this region of the heart.

“In the past, we tended to think of the left atrial appendage as insignificant,” said Lourdes electrophysiologist Darius Sholevar, MD. “But in AFib patients, we now recognize it as the primary source of blood clots and strokes.”

**Placed via Brief Catheterization Procedure**

In patients with normal heart rhythm, the atrial appendage contracts with the rest of the left atrium, ejecting its full volume of blood into the left ventricle. In AFib, the LAA may retain blood and be subject to increased stasis. Clots that form in this structure may eventually dislodge and reach the brain, causing stroke.

“When dislodged from the appendage, the majority of such clots travel to the brain.” said Lourdes electrophysiologist Devender Akula, MD, FACC. “Estimates are that clots causing stroke in AFib patients originate in the left atrial appendage about 90 percent of the time." For this reason, patients with AFib must be on therapy with anticoagulants such as Coumadin or newer anticoagulants, with all the inherent risks and precautions of this class of drugs. Trans-esophageal echocardiography (TEE) has made clear imaging of the LAA possible, so that the electrophysiology team can assess the size, shape and flow patterns of the appendage. In the lab, the team catheterizes the patient’s femoral vein and, guided by fluoroscopy and TEE, gains access to the LAA from the right atrium through a small puncture across the atrial septum into the left atrium. The specialists then lodge the self-expanding mesh disc in place to close off the LAA. (See figure.)

**The First Proven Alternative to Blood Thinners for AFib**

Within weeks, tissue grows over the Watchman device, securing it in place, and the septal puncture heals quickly. Clots may still form in the appendage, but will not be released.

The PROTECT AF trial, completed in 2014, showed that the Watchman device was as effective as Coumadin in reducing the risk of stroke in AFib patients. “Watchman is the only device that has proven equal to blood thinners for stroke reduction in the population of patients with AFib not related to heart valve disease,” said Dr. Sholevar.

The Watchman procedure takes about an hour, and patients stay overnight in the hospital. At home, patients remain on anticoagulant therapy for 45 days and, if follow-up TEE confirms that the appendage is blocked, then continue on aspirin and Plavix for six months. After that, only a daily aspirin is needed.

“Individuals with AFib are at high risk for stroke, and the risk increases with time,” said Dr. Akula. “This device can change the lives of AFib patients who do not tolerate blood thinners.”
A study led by Lourdes and reported internationally has shown that the pacing lead for implantable cardioverter defibrillators, or ICDs, can be placed within the chest, without the need to position it directly in the cardiac vasculature. The Substernal Pacing Acute Clinical Evaluation (SPACE) study found that the extravascular (EV) ICD is capable of pacing the heart—thus potentially avoiding the need to place leads into the heart itself. EV ICDs are projected to have a longevity of approximately 10 years and are being designed to prevent the rare, but potentially serious, risks that can occur when leads are implanted inside the vasculature and the heart.

“The EV ICD also has the potential to be more effective than current subcutaneous ICD lead placement in its role as a pacemaker,” said Dr. Sholevar, principal investigator of the multi-center SPACE study. “In this pilot trial, we showed that the EV approach may avoid the issues experienced with both intravascular and subcutaneous lead placement.”

ICD leads implanted transvenously into the heart can sometimes prove challenging to place. In addition, wires can break, malfunction or be involved in infections. Lead revision and extraction procedures are feasible and generally safe, but are associated with risks. Currently, subcutaneous ICD leads placed subcutaneously can deliver post-shock pacing therapy only. In doing so, though, they typically also pace the muscle wall, which can be uncomfortable in conscious patients. Due to lead position outside the chest wall, the device is also larger so that it can deliver a higher-energy shock. The subcutaneous ICD system has a short lifespan and cannot offer other types of pacing.

The SPACE trial used an I.V. placed under the breast bone to access the soft mediastinal tissue in front of the heart. The electrode strip was centered over the right ventricle. In the SPACE study, presented at two conferences this year in San Francisco and France, a majority of patients achieved consistent and appropriate ventricular pacing results with EV leads. In the Acute Substernal Defibrillation (ASD) study, results showed that EV ICDs required much less energy for defibrillation than do subcutaneous ICDs.

“An ideal scenario would be to use substernal leads to provide both low-energy defibrillation and on-demand bradycardia pacing for all patients who receive a device,” said Dr. Akula, who was a coauthor in the SPACE study.

For more information, visit www.lourdesnet.org or call 1-888-LOURDES (1-888-568-7337).