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Loyola to conduct clinical trial of new procedure to treat atrial fibrillation

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Loyola Medicine is enrolling patients in a landmark clinical trial of a new procedure to treat atrial fibrillation, the most common type of irregular heartbeat.

The clinical trial will combine the standard catheter ablation treatment for atrial fibrillation (AFib) with a new procedure called a Lariat left atrial appendage ligation, in which a physician uses a tiny lasso to tie off a thumb-size pouch attached to the heart.

The primary purpose of the study is to determine whether the combined Lariat/ablation treatment is more effective in eliminating AFib at 12 months than ablation alone.
A second potential benefit of the Lariat is in reducing the risk of life-threatening blood clots. AFib patients who are at risk for such clots typically are put on blood thinners such as warfarin (Coumadin®). "By eliminating a main source of blood clots, the Lariat procedure can be particularly beneficial to patients who cannot tolerate blood thinners," said Loyola electrophysiologist Smit Vasaiwala, MD. (An electrophysiologist is a cardiologist who treats heart rhythm disorders.)

In a Loyola pilot study that helped pave the way for the trial, Dr. Vasaiwala recently performed the Lariat procedure on Gerald Primozic, a semi-retired executive from Homer Glen, Illinois. Mr. Primozic could not take blood thinners because he was at risk for a brain bleed. Thus, he was a perfect candidate for the Lariat procedure, according to Dr. Vasaiwala.

In addition to performing the Lariat procedure, Dr. Vasaiwala, assistant professor in the division of cardiology at Loyola University Chicago Stritch School of Medicine, treated Mr. Primozic's AFib with the standard catheter ablation treatment.

"I went home the next day and feel great," Mr. Primozic said. "My only discomfort was some soreness where one of the catheters was inserted."

An estimated 2.7 to 6.1 million Americans - including 9 percent of those over age 65 - have AFib, according to the U. S. Centers for Disease Control and Prevention. Symptoms include heart palpitations, lightheadedness, fatigue, shortness of breath and chest pain. AFib increases a person's risk for stroke by four to five times.

In AFib, electrical signals that regulate the heartbeat become erratic. Instead of beating regularly, the upper chambers of the heart quiver and blood doesn't flow well. Some of the erratic electrical signals originate in the troublesome thumb-size pouch, called the left atrial appendage. In the new Lariat procedure, an electrophysiologist uses two catheters to tighten a loop of suture material - similar to a lasso - around the base of the left atrial appendage. This seals the appendage off from the rest of the heart. The appendage shrivels up and becomes harmless scar tissue.

The clinical trial, called aMAZE, will enroll as many as 600 AFib patients at as many as 50 centers nationwide. One group of patients will be randomly assigned to undergo the Lariat procedure in addition to receiving catheter ablation. They will be compared with a control group of AFib patients who will undergo catheter ablation alone.

In patients with a normal heartbeat, the left atrial appendage squeezes with the rest of the heart, ejecting blood with each beat. But in patients with AFib, the appendage no longer rhythmically contracts, creating a sluggish blood flow that can cause blood to pool and clot. Blood clots subsequently can travel to the brain and cause strokes. The appendage also contains many of the sources that maintain AFib, so eliminating it also may reduce the risk of future AFib recurrences.

Dr. Vasaiwala said patients who undergo the Lariat procedure are relieved to go off blood thinners. The medications increase the risk of bleeding and bruising and restrict participation in activities such as contact sports. Blood thinners can cause stomach pain and other side effects. The medications also are expensive, costing up to $300 per month.

Source:
Loyola University Health System