

LARIAT PROCEDURE A POTENTIAL LIFESAVER FOR ATRIAL FIBRILLATION PATIENTS

A 78-year-old woman with atrial fibrillation recently came to the University of Maryland Medical Center in deep fear: The blood thinner she was taking to avoid a stroke — which may occur from <2% up to 20% of untreated atrial fibrillation (AF) patients — had triggered a hemorrhage in her gastrointestinal tract that required nine units of blood to treat. The woman’s husband had also died of a stroke, further terrifying her. What would be the best solution?

Fortunately, UMMC had become one of a handful of institutions in the mid-Atlantic region to offer a groundbreaking procedure that essentially ties off the predominant clot-forming portion of the heart in AF patients, sparing them the need to take blood thinners with the goal of lowering their stroke risk. Known as left atrial appendage (LAA) ligation, the percutaneous procedure uses a device called a LARIAT to place a

suture around the base of the LAA, permanently sealing it off from the rest of the heart and stopping stroke-causing blood clots from traveling to the brain.

The woman was the first UMMC patient to benefit from the procedure, performed last August by a UMMC team consisting of interventional cardiologist Mukta Srivastava, M.D.; cardiac electrophysiologist Vincent See, M.D.; cardiothoracic surgeon Murtaza Dawood, M.D.; cardiologist Christopher DeFilippi, M.D.; and cardiac anesthesiologist Phillip Roman, M.D. Approved by the FDA in 2008, the LARIAT has been implanted in an estimated 1,400 AF patients in the United States and Poland, its initial study site.

“This is a new technology providing people an alternative for stroke protection when they can’t take blood thinners,” explains Dr. See, also an Assistant Professor of Medicine. “For people with limited options, it may be a

useful tool to minimize their stroke risk. It offers peace of mind when their options are limited. Certainly it’s something we’re excited to offer our patients.”

DEVICE WORKS ‘LIKE A COWBOY’S LASSO’

Atrial fibrillation — a condition in which the heart beats irregularly — affects an estimated three million Americans, raising their stroke risk to five times the normal rate. Since stroke is the third-leading cause of death in AF patients, the LARIAT procedure represents a potentially lifesaving breakthrough. AF patients — typically older adults who often suffer from other chronic conditions such as diabetes and hypertension — are routinely prescribed powerful anticoagulants such as warfarin (Coumadin), rivaroxaban (Xarelto), apixaban (Eliquis) or dabigatran (Pradaxa), but such prescriptions may be expensive or require frequent medical visits and blood tests to monitor levels.

For AF patients with a history of bleeding complications or intolerance of anti-clotting drugs, the LARIAT procedure is an alternative that targets the specific part of the heart that most explains stroke in AF without affecting the rest of the heart. A one-time solution, the procedure is performed under general anesthesia using two catheters. The first, which carries the LARIAT device, is threaded under the patient’s rib cage and into the pericardium; the second is threaded through the groin and crosses over to the heart’s LAA, helping guide the LARIAT into place. Once there, X-rays and



DRS. VINCENT SEE AND MUKTA SRIVASTAVA use the LARIAT procedure.

- UMMC named a start-up location in mid-Atlantic region for groundbreaking LARIAT procedure
- LARIAT device places suture in left atrial appendage (LAA), the source of many blood clots among atrial fibrillation (AF) patients
- Procedure a strong alternative to anticoagulants for AF patients who can't tolerate drug regimen
- UMMC team performed first LARIAT technique August 2013
- Two other devices for LAA occlusion currently under development

echocardiograms ensure the device is properly placed, where a loop stitch is tightened around the base of the LAA.

"The LARIAT is literally like a cowboy's lasso, meant to slip over the structure of the left atrial appendage," Dr. See says. "That structure is like an appendix — no one really has a good explanation why we need it anymore, but everyone has one. About 80-90% of clots that create an issue in AF patients may originate there, according to prior research."

Though UMMC physicians have done only one LARIAT procedure so far — on the 78-year-old patient — they hope to eventually offer the device to more patients who may benefit from a mode of stroke protection when they are unable to tolerate traditional anti-coagulation therapy, according to Dr. Srivastava, also an Assistant Professor of Medicine and Associate Program Director of the General Cardiology Fellowship.

"We estimate that 20% of elderly a-fib patients have some type of contraindication for using blood thinners due to a history of GI bleeding, non-compliance or a history of intracranial bleeding, and are unprotected for stroke risk," she says. "For these patients, this procedure offers some protection. While it is a minimally invasive, percutaneous procedure, two access sites are utilized, along with multiple imaging modalities and a multi-disciplinary approach."

FIRST PATIENT FULLY RECOVERS

As with any cardiac procedure, the LARIAT technique inherently carries major risks including heart attack, stroke and death. But the biggest complication risk specific to this procedure is puncturing the heart muscle itself as the needle it employs passes into the pericardium. If that happens — which is infrequent — LARIAT procedures may need to be converted to open heart surgery to fix the damage.

Other more minor complications can include post-procedure pain and inflammation, and patients may still suffer a blood clot or stroke in the future from causes other than their left atrial appendage, Dr. See explains.

Two other devices to occlude the left atrial appendage in AF patients are under development, so a greater array of solutions for the problem is on the horizon. All essentially block the physical connection between the rest of the heart and the LAA, which in animal models tends to atrophy afterward.

"Some say the risk of puncturing the heart may be up to a 5% to 6% range, which, depending on your outlook, is a single-digit percentage but also not 1%, which is closer to the risk of some other arrhythmia procedures we perform," Dr. See says. "So there are still some concerns."

The UMMC team's first patient happened to suffer that complication, lengthening the LARIAT procedure

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- VINCENT SEE., M.D.

and prolonging her hospital stay to four days from the norm of one or two. But after a month-long recovery period at home, the woman has fully regained her energy and achieved maximum benefit from the procedure, Dr. Srivastava says.

"She is back to her baseline, doing what she did before and the procedure is a distant memory now," Dr. Srivastava says. "In her age group, loss of independence is the biggest fear, which can result from a debilitating stroke — and this definitely hung over her. She expressed relief that she's potentially protected from stroke now." +



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