NMMC Physicians Implant State's First Vagal Nerve Stimulator for Heart Failure

The Associated Press

Doctors at North Mississippi Medical Center recently implanted the state's first vagal nerve stimulator as part of a clinical research study to treat heart failure through nerve stimulation in the neck.

According to cardiac electrophysiologist Karl Crossen, M.D., and neurosurgeon Louis Rosa, M.D., research demonstrates a connection between the heart and brain that could benefit heart failure patients. Last fall, 61-year-old Jack Aldridge of Mooreville and 59-year-old Annie Richardson of Tupelo became two of NMMC's first patients to benefit from that research and receive the CardioFit® implantable electrical stimulation device.

Vagal nerve stimulation therapy has been used for years to control seizures in epilepsy patients and more recently for treating drug-resistant cases of clinical depression. Drs. Crossen and Rosa are leading NMMC's participation in the INOVATE-HF clinical trial, the first time vagal nerve stimulation is being used to treat congestive heart failure.

Aldridge's heart problems began late in 2011. "I was very weak. I couldn't walk anywhere without having to sit down," he said. "I would have to sit up on the edge of the bed to breathe because I couldn't breathe lying down too well. I had a heaviness on my chest."

Tests revealed his heart had a leaky mitral valve as well as two blocked arteries. He underwent mitral valve repair and heart bypass surgery in November 2011. After surgery, he experienced complications that required a second surgery and a long recovery process. Then he was diagnosed with congestive heart failure, meaning his heart is unable to pump enough blood to sustain adequate circulation. At the time his ejection fraction, or heart's pumping ability, measured only 25 to 30 percent.

Richardson suffered her first heart attack seven years ago and a second one in May 2012. "The second heart attack was a hard one," she said. "It damaged my heart a lot." Because of the extensive damage, Richardson's heart was pumping at only 10-15 percent.

Dr. Crossen explains that the brain helps control the function of the heart through two branches. The sympathetic branch activates the "fight or flight" response during stress, increasing heart rate and blood pressure. The parasympathetic branch has a calming effect on the heart through signals carried from the brain to the heart by the vagus nerve. Normally the two branches are in balance. In congestive heart failure, there is an imbalance.

"In heart failure as the pump function weakens, the body attempts to adapt by using the adrenaline -- or sympathetic -- nervous system in the same way that when someone exercises the body uses adrenaline to increase heart rate and cardiac contraction," Dr. Crossen said. "We now know that these adaptations over long periods of time are detrimental."

Like driving a car, easing up on the accelerator (sympathetic) will slow down the car a bit, but stepping on the brake (parasympathetic) will reduce the speed more quickly. Some heart failure medications help to "slow down" the sympathetic branch, but currently there are no proven treatments that help an underactive parasympathetic branch.

"Medications such as beta blockers, which block the sympathetic system, are associated with improved outcomes in heart failure. At the same time that this system is ramping up to respond to worsening heart failure, the parasympathetic system is suppressed in heart failure patients," Dr. Crossen said. "There is no medication that predictably increases the effect of the parasympathetic branch to bring better balance to the heart. Stimulating the vagus nerve in the right side of the neck can directly raise the parasympathetic effect on the heart and is the basis for this new treatment."

The goal is to decrease the workload on the heart, giving it a chance to heal. As the heart becomes more effective, patients should be better able to tolerate activity. The clinical trial will assess whether combining vagal nerve stimulation and medication is more effective than medication alone. "Because the FDA is still monitoring how well this will work, they need something to compare it to," Dr. Crossen explained. "Three out of every five patients in the trial are randomly selected to receive the vagal nerve stimulator, and then we follow all five of the patients -- both those who got the implant and those who did not -- to see how their outcomes compare."

Drs. Crossen and Rosa operate together in NMMC's hybrid operating room -- a cross between a cardiac catheterization laboratory and a surgery suite -- to implant the vagal nerve stimulator, and many patients also have an internal cardiac defibrillator implanted at the same time to shock the heart back into normal rhythm if necessary. Like a traditional pacemaker, the vagal nerve stimulator is placed under the skin of the chest and attached to the heart -- but it is also connected to a nerve on the right side of the neck. The device sends electrical pulses to the nerve, which sends signals to the heart.

Right away Aldridge, who enjoys working on his own vehicles and doing yardwork, could tell a difference. "I was fighting for every breath I could get. It has helped me tremendously," he said. "Things I couldn't do before, I'm more able to do now. It has given me more strength and a better outlook on life."

Richardson agrees that the device is making a difference. "I feel pretty good," she said. "I'm glad I have it."

For four to six weeks after the procedure, patients come in weekly to have their

device titrated. "We condition the patients by starting out with the electrical impulses very low and then gradually increase them," Dr. Crossen said.

NMMC is one of only 22 sites in the United States and 36 sites worldwide participating in the INOVATE clinical trial. Outside Tupelo, the closest sites are in Birmingham, Ala.; Orlando, Fla.; Atlanta, Ga.; Houston, Texas.

Heart failure is also the leading cause of hospitalization in people over 65. "Heart failure has a high mortality rate and significantly limits a patient's ability to live a normal life," Dr. Rosa said. "Our goal is to help the patient by providing increased heart function and improving quality of life."

For more information about NMMC's participation in the INOVATE clinical trial, call the NMMC Heart Institute at 1-800-THE DESK (1-800-843-3375).