Study investigates Gore-tex-type device to stop strokes and mini-strokes

November 18 2008

A study is under way at Rush University Medical Center using a small, soft-patch device made of a Gore-tex-type material – often used to make durable outerwear – to close a common hole found in the heart called a patent foramen ovale (PFO) in order to prevent recurrent strokes and transient ischemic attacks (TIAs) in adults.

Rush is the only academic medical center in the Chicago area involved in the trial and one of only 50 sites in the U.S. and the world.

The randomized, multinational clinical research trial may determine if repairing a PFO using this device, also known as the GORE HELEX Septal Occluder, is more effective in preventing strokes than medical management alone. The U.S. Food and Drug Administration (FDA) recently granted approval to use the device for PFO closures. It is currently approved by the FDA for the treatment of atrial septal defects (ASDs), a congenital heart defect found in young children.

"This PFO-closure device uses a biocompatible material that allows progressive tissue growth to help seal the defect," Dr. Ziyad Hijazi, director of the Rush Center for Congenital and Structural Heart Disease and co-investigator of the clinical trial at Rush. "It shows promise because of its soft, flexible design that has the ability to conform to a patient's anatomy."

The miniature umbrella-like device is fed through a catheter that is placed in the vein of the patient's leg using just one small puncture. The

catheter is led through the vein up to the heart where the device is placed to seal the flap.

"Everyone is born with a PFO, which normally closes after birth "said Hijazi. "But in one in five Americans, the closure process is incomplete allowing blood returning from the body to bypass the filtering system of the lungs and enabling blood clots to travel from one area of the body through the heart and up to the brain causing a stroke."

Most often, patients do not show any signs or symptoms, and a PFO can go undetected through adulthood. It is not until a patient experiences a stroke that a PFO defect is often diagnosed. Many of these strokes occur in people under the age of 50.

"Stroke has many causes. Unfortunately, in approximately twenty-five percent of cases, we do not find a specific cause. It has been suggested that in these cases, which are referred to as cryptogenic stroke, PFO might be a potential risk factor," said Dr. Vivien Lee, stroke neurologist and study co-investigator at Rush. "The question we are trying to answer with this study is whether a PFO closure can reduce the risk of recurrent stroke."

The purpose of the study is to help patients like Nathan Prince, a 31-year-old truck driver from Justice, Ill., who learned he had a congenital hole in his heart after suffering two strokes in three days.

"I was completely shocked," said Prince. "I kept thinking I am way too young. I never experienced any symptoms. I am pretty athletic and always on the go. All of this seemed so sudden."

Prince was immediately put on anticoagulants and other medication. "I was pretty upset when I found out that I had to take all this medication," said Prince. "I mean, I am a young guy and now I have to take all these

medicines and who knows what the long term effects could be."

Prince's neurologist referred him to Rush University Medical Center to see Hijazi. "When Dr. Hijazi explained to me that I could have a procedure that could close up that hole, stop my stroke symptoms and be home the next day, I immediately asked how soon we could do the procedure," said Prince.

The same afternoon as his procedure, Nathan was up, reading, moving around and ready to go home.

"I'm just happy that I won't have to be on all those medications anymore," said Prince.

Currently, the primary treatment option is medical management.

"This study may provide useful information that will help us determine a new possible standard of care for stroke patients," said Lee. "We have medications options that work well in reducing a stroke patient's risk of recurrence, but now we can see if PFO closure is an additional option that may also be beneficial to stroke patients.

Source: Rush University Medical Center