

Repairing Mitral Valves Without Surgery



EARLY LAST YEAR, Emily Pierce, a 36-year-old mother of four from Westchester County, N.Y., began to notice that she couldn't keep up with her regular workouts. A few weeks later, when just two minutes on the treadmill left her winded, she went for a checkup.

The diagnosis: mitral regurgitation, a condition that occurs when the two triangular-shaped leaflets of the heart's mitral valve don't close tightly. This allows blood to regurgitate (flow) backward from the left ventricle into the left atrium, taxing the heart.

Emily's cardiologist recommended that the valve be repaired or replaced, which meant open-heart, or at least minimally invasive, surgery. With four young children to chase after and a household to run, she was reluctant to have a major operation. But

without it, her heart would weaken and enlarge, ultimately leading to congestive heart failure.

Emily chose not to have surgery, yet she is doing well and her prognosis is good, according to her physician. In late October she came to NYU Medical Center to undergo an investigational procedure, available only through FDA-approved clinical trials, in which the mitral valve is repaired percutaneously (i.e., through the skin), employing techniques similar to those used in cardiac catheterization.

During the procedure, a sheath is threaded into the femoral vein in the groin until it reaches the right atrium, one of the upper chambers of the heart. Next, a catheter is used to puncture the septum, the structure that separates the right and left atrial chambers, providing access to the left atrium and the mitral valve. (Most punctures heal in 6 to 12 months.) A steerable catheter, equipped with a special clip, is then inserted into the sheath and guided toward the mitral valve.

When the valve leaflets are grasped and the regurgitation reduced, the clip is deployed, allowing the valve to close properly and the normal direction of blood flow to proceed.

The clip, about half an inch long and made of metal and covered with polyester, is used to mimic a valve-repair technique, in which the edges of the two leaflets are partially sutured together. However, that valve-repair technique requires a conventional surgical approach

through the chest wall in order to gain access to the valve and requires putting the patient on a heart-lung bypass machine.

"Judging by our initial experience, it is now possible to do a similar edge-to-edge repair percutaneously," says James N. Slater, M.D., Associate Professor of Medicine, who performed the procedure on Emily. "This option may spare the patient the trauma of surgery and the need to be put on a heart-lung bypass machine."

As with cardiac catheterization, the procedure carries a slight risk of heart rhythm disturbances, bleeding, stroke, and infection, among other complications, though

Evalve, Inc., of Menlo Park, Calif. — in the management of patients with mitral regurgitation remains to be seen. The percutaneous option may also encourage more patients with mitral regurgitation to get definitive treatment earlier. Drugs can be prescribed to alleviate the symptoms, but they do not correct the underlying problem. "If you leave severe mitral regurgitation alone, it gets worse and worse," says Dr. Slater. "Eventually, the heart muscle enlarges and you go downhill pretty quickly. If you wait too long, the surgical results are not as good."

As for Emily, she is faring well. "Her mitral regurgita-



AN EXPERIMENTAL PERCUTANEOUS PROCEDURE REPAIRS THE MITRAL VALVE WITHOUT OPENING THE CHEST. THE INTERVENTIONAL CARDIOLOGIST STEERS A CATHETER EQUIPPED WITH A SPECIAL CLIP TO THE VALVE (SHOWN IN WHITE ABOVE). ONCE IN PLACE, THE CLIP ALLOWS THE VALVE TO OPEN AND CLOSE PROPERLY.

few complications were reported in early evaluations of the device. Phase II clinical trials of the procedure are now being conducted at NYU Medical Center and some 30 other sites in the United States and Canada.

The overall role of the device—which is called the MitraClip and is made by

tion went from very severe to moderate," reports Dr. Slater. "She is asymptomatic at this time."

"About a month after the procedure," says Emily. "I started to get my energy back. I wasn't out of breath any longer. I felt like a new person." ●

— Gary Goldenberg