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Contact: Tiffany Jones, DMC
(313) 460-6416 cell

Detroit-Area Retiree Badly Needed Valve Replacement -- But Was Too Weak to Undergo Open-Heart Surgery

DETROIT – For Shirlene Stephens, a struggling grandmother with a defective heart valve, it was literally a matter of life or death.

No matter how often the retired Detroit-area pump-equipment assembler reviewed her desperate situation, the stark reality always looked the same.

At the age of 72, the normally upbeat and cheerful grandmother of two was suffering with a condition known as “aortic valve stenosis” . . . a potentially fatal ailment in which abnormal narrowing of the crucially important aortic valve shuts down the flow of life-giving blood from the heart to the rest of the body.

Unfortunately for Ms. Stephens, the condition was irreversible and progressive.

Her aortic valve had been severely crippled by the disorder – and her only hope was an open-heart surgical procedure to replace the damaged valve with a new prosthetic version. Installing such a device would allow normal blood-flow to exit her heart and then go about its vital business of supplying oxygen to the tissues all through her body.

But then she got some very bad news. Because she also suffered from a *second* major health condition – severe emphysema – she was told that she would never be able to tolerate the harsh rigors of “chest-cracking” open-heart surgery.

Describing her plight recently, Ms. Stephens shook her head. “It was very difficult at times,” she said. “I was stuck, that’s all, and my situation seemed to be getting worse by the day. I prayed a lot, and everybody at my Methodist Church was praying for me, too.”

As one of the more than 100, 000 Americans who struggle with severe aortic valve stenosis each day, Ms. Stephens had educated herself carefully about the disorder. She knew, for example, that if the ailment were left untreated, research shows that 50 percent of patients die within one year.

She also knew that fully one third of America’s severely affected aortic stenosis patients were like her – ineligible for the open-heart surgery that would be required to replace her failing valve and restore her to healthy, vigorous functioning.

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As her condition slowly worsened during the past decade or so, Ms. Stephens consulted several specialists. “I tried to get help, but they didn’t really listen to me and after a while I didn’t know where to turn,” she recalls.

It was awful, she says. But then she finally got a break.

During a recent conversation with her longtime cardiologist, Dr. Theodore L. Schreiber, she learned about a new “clinical trial” that was just getting underway at the Detroit Medical Center (DMC) Cardiovascular Institute (CVI).

The clinical trial, approved by the U.S. Food and Drug Administration (FDA), is designed to evaluate the safety and effectiveness of the Medtronic CoreValve® System, a device that does not require surgery. The trial will evaluate both patients at high risk for surgery and patients, like Stephens, who are inoperable, or at “extreme risk” for surgery.

Once she got the news, Ms. Stephens didn’t hesitate. Acting quickly, she made an appointment to sit down with Dr. Schreiber, the CVI president and also the medical supervisor of the new DMC clinical trial for non-surgical heart valve replacement.

“We talked for nearly an hour,” Ms. Stephens would recall later, “and Dr. Schreiber explained the procedure in detail. He told me exactly how the replacement would work – and that instead of cutting my chest open, his medical team would simply insert the new valve into an artery in my leg, and then guide it gently into place.”

The procedure had a fancy scientific name – a “transcatheter aortic valve implant,” or “TAVI” – but the bottom line was simple and easy to understand. Once the new aortic valve was inserted into Shirlene’s old, damaged one, it would immediately begin to do the job that was required to move life-giving, oxygen-rich blood throughout her body.

And that’s exactly what happened next.

During a two-hour procedure in a DMC Harper University Hospital “catheterization lab” a few days ago, Dr. Schreiber and his colleagues carefully guided the new Medtronic CoreValve Transcatheter Aortic Valve into place, deep inside Shirlene Stephens’ heart.

And the results?

Within a matter of seconds, the new valve was performing normally.

And because she hadn’t been forced to undergo the rigors of open-heart surgery, Ms. Stephens was soon up and about.

Now she’s looking forward to returning home to her pleasant, tree-lined neighborhood in the New Baltimore section of Macomb County.

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“I feel like I’ve been through a miracle!” says the still beaming grandma today. “I’ve got more energy than I’ve felt in a long time, and my emphysema even seems to have improved. I can’t thank Dr. Schreiber enough for making this so easy for me.”

Ms. Stephens says she’s “really excited” about visiting with her first great-grandchild, once she gets back home. And she’s “especially eager” to resume her “daily walks with Zoie,” her long-haired miniature dachshund.

Dr. Schreiber, meanwhile, says he’s “very hopeful” that the new non-surgical valve-replacement therapy he provided Ms. Stephens will soon be helping hundreds of other patients like her.

“We hope this clinical trial will result in a significant treatment advance for patients with aortic stenosis who can’t tolerate open-heart surgery,” said the CVI president and veteran cardiac specialist. “It’s also the first procedure of its kind to ever take place in Michigan.

DMC Cardiovascular Institute is currently enrolling patients in the trial. For more information about participating in this clinical trial, call 1-(855) VALVEMD or 1-(855) 825-8363.

Physicians are available for interviews.

For broadcast quality animation, photos and bios, visit www.DMCCVI.org/aortic.

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