Special Report

Transcatheter Aortic Valve Replacement:

A Physician-Patient's Story

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ntil several months ago, I had severe aortic stenosis. Then something remarkable happened. I received a new aortic valve without having my chest opened. And more good things were to come. I would go home the next day, be back in my office 72 hours later, and resume full activities (including daily runs on my treadmill) less than 2 weeks after undergoing a transcatheter aortic valve replacement (TAVR). Immensely gratified by this sequence of events, I thought that the specifics of my case might prove interesting and be of value to candidates for a TAVR and to their doctors as well. Hence, this report.

Relevant History

In September 2003, at the age of 74 years, I was symptom-free, running 14 miles a day on the treadmill, eating a low-salt, low-fat, and low-sugar diet, and taking a low-dose aspirin daily as my only medication. I weighed 150 lb, stood 5 ft. 10½ in. tall, had a blood pressure of 120/70 mmHg in both arms, and didn't smoke or consume alcohol. My complete blood count, metabolic panel, urinalysis, and chest film gave normal findings, and my electrocardiogram showed a previously documented right bundle branch block. A transthoracic echocardiogram (TTE), my first, disclosed mild sclerosis of a trileaflet aortic valve but was normal otherwise.

During the subsequent years, I maintained the same diet, kept the same weight and blood pressure, and ran approximately the same number of miles daily. All of my aforementioned tests continued to give the same results. In January 2012, however, my TTE showed a change. What initially was mild sclerosis had become mild stenosis of the aortic valve. In addition, the valve area had decreased, the gradient across the valve had risen, and a honking systolic murmur had emerged. The murmur could be heard all over my precordium, loudest at the apex.

In the 18 months preceding the TAVR, I began to lose my strength and stamina. Consequently, I reduced my running pace, limited my distance to 6 miles or less each day, and needed more sleep. In addition, putting on my thigh-high support hose became a struggle and often left me short-winded. I figured that these developments were products of aging and didn't give them much thought.

By March 2015, the gradient across my aortic valve had reached 70 mmHg (mean, 42 mmHg), the valve area had decreased to 0.8 cm², and the peak velocity across the aortic valve was 4.19 m/s. The left ventricular ejection fraction remained normal at 0.60. Although I did not consider myself symptomatic at the time, these numbers called for surgical intervention¹—open-heart or TAVR.

Historically, the recommended treatment for severe aortic stenosis has been surgical aortic valve replacement (SAVR).² But many prospective candidates for SAVR are of advanced age and have various comorbidities that make them inoperable or at high risk for that procedure. On the basis of calculations from the Society of Thoracic Surgeons³ and the Valve Academic Research Consortium,⁴ my doctors classified me at intermediate risk. Nevertheless, because I have significant kyphosis, they thought that a SAVR was not the best option for me. They recommended, instead, a TAVR, using the transfemoral approach. There was no medical reason for them to recommend any of the less commonly used access routes—transapical, transaortic, subclavian, or transaxilliary.⁵

Preoperative Evaluation

To qualify for a TAVR, I agreed to be part of the PARTNER II trial, a research study of up to 1,000 patients in a minimum of 60 hospitals. The purpose of the study—spon-

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© 2015 by the Texas Heart® Institute, Houston sored by Edwards Lifesciences, LLC (Irvine, Calif)—is to determine the safety and effectiveness of the Edwards SAPIEN® 3 Transcatheter Heart Valve (THV) Model 9600TFX. The valve has not yet been approved for commercial use by the U.S. Food and Drug Administration or by any other governmental agency in North America.

In accordance with protocol, I had to undergo a series of designated tests and procedures. These included a physical examination, a TTE, pulmonary function tests, a variety of blood tests, coronary angiography, and computed tomographic angiography of the chest, abdomen, and pelvis. This last study provides important information regarding the size, integrity, and tortuosity of the femoral and iliac arteries and of the abdominal and thoracic aorta. That information helps to determine the proper size of the valve to be implanted and the condition of its pathway to the heart. In my case, those arteries appeared to be normal in size and shape, with little evidence of atherosclerotic disease. In striking contrast, the coronary angiogram showed a 30%-40% stenosis in the mid-segment of the dominant right coronary artery and a 90% stenosis in the mid-segment of the left anterior descending coronary artery. For the latter lesion, I received a XIENCE® Everolimus-Eluting Stent (Abbott Vascular; division of Abbott Laboratories; Abbott Park, Ill) along with a platelet inhibitor, a statin drug, and the low-dose aspirin.

TAVR Procedure

On 8 April 2015, I received my new aortic valve (size, 26 mm; serial no. 4186721) through the right femoral artery. The valve has a fabric skirt, a stainless-steel frame, and 3 leaflets made from bovine pericardium. Members of the operating team were an anesthesiologist who gave me general anesthesia, 2 interventional cardiologists who performed the TAVR, and a cardiac surgeon and cardiac electrophysiologist, each poised to render assistance if needed. Also present were an interventional cardiology fellow, 2 nurses, and a representative from Edwards Lifesciences.

Once asleep, I had catheters inserted in both femoral arteries and the right radial artery, 2 separate lines in my left femoral vein, and a probe in place for transesophageal echocardiography. A step-by-step description of what happened next is beyond the scope of this report; details of that nature, including possible complications, are available elsewhere. Suffice it to say, everything was done in intravascular fashion under fluoroscopic guidance. An inflated balloon broke apart the stenotic leaflets of my native aortic valve, making room for the new compressed valve. To achieve proper positioning and expansion of the new valve, my cardiac output was minimized temporarily by accelerating my heart rate to 180–220 beats/min. After the valve was securely in place, a transesophageal echocardiogram confirmed

that it was functioning well. At the end of the procedure, the mean gradient across the valve was 4 mmHg, and the precordial murmur had disappeared. The actual operating time was an unbelievably short 20 minutes.

Postoperative Course

I spent the first 10 hours in the intensive care unit and the remaining hours in an intermediate-care bed. Early the next morning, a chest film showed the valve and coronary stent in place. A TTE also showed the valve to be well seated, with trivial aortic regurgitation and mild pulmonary hypertension. The mean gradient across the valve was 7 mmHg, the peak velocity was 1.91 m/s, and the valve area was 1.89 cm².

Later that day at home, I noticed an ache in the arch and lateral side of my right foot. Those areas were tender to touch but bothered me only when I walked. The discomfort persisted for 4 days, then rapidly went away. I believe that it was a distal manifestation of femoral nerve irritation, brought about by the insertion of a large-bore catheter into the adjacent femoral artery.

The only other sequela was extensive bruising of the skin in the pelvic area. It was particularly prominent over the inner aspects of both thighs and over my genitals. The bruising took a week to reach its maximal intensity and 5 weeks to resolve completely. My catheter-insertion sites were sore for a few days but healed uneventfully.

At my 30-day follow-up evaluation, a TTE showed that my new valve was functioning well and that the previously documented mild pulmonary hypertension had resolved. There were no other changes of note. The next scheduled follow-up evaluation is at one year.

Looking Back

My TAVR was an amazing and uplifting experience. I never dreamed that getting a new aortic valve could be so easy and recovery from it so rapid—and pain-free as well. I escaped the 2 sequelae that I had feared the most, stroke and the need for a permanent pacemaker. The sequelae that I did incur—transient ache and tenderness in my right foot and extensive pelvic bruising—were small physical prices to pay for a new aortic valve.

With regard to the real price, my TAVR cost a total of \$161,405.82. That figure includes placement of the coronary stent and all other preoperative and postoperative care. Thankfully, my insurance carriers paid the entire bill.

When I reflect on my slowdown in the months preceding the TAVR, I see things differently now. The slowdown was not the consequence of my aging as I had thought, but almost certainly was the result of my severe aortic stenosis. Within days after the operation, I had regained much of my strength, could put on my support hose without struggling or becoming winded, and found my treadmill running to be easy again.

Another major but unexpected benefit of my TAVR was the placement of a stent in my left anterior descending coronary artery—"the widow-maker." Fortunately, coronary angiography was a requisite for the procedure. Otherwise, I wouldn't have known or even suspected that I had such a time bomb in my chest. After all, I had led the perfect heart-healthful lifestyle for more than 50 of my adult years, had never noticed chest discomfort of any sort, and had ranges of lipid values that were ideal and supposedly protective (high-density-lipoprotein cholesterol, 70–103 mg/dL; low-density-lipoprotein cholesterol, 55–80 mg/dL; and triglycerides, 29–60 mg/dL). So, in a strange and subtle way, severe aortic stenosis can sometimes play 2 dichotomous roles simultaneously—outright threat and indirect savior.

Considering the findings on my coronary angiogram, I wondered whether my long-standing efforts to thwart the onset and progression of atherosclerotic disease had been in vain. I decided that, without those efforts, I wouldn't be alive today.

Current Standings

Beginning with the first report of a TAVR in 2002,6 more than 70,000 transcatheter valves have been implanted worldwide. Evidence to date supports TAVR especially by means of the transfemoral approach—as an alternative to SAVR in high-risk patients with severe aortic stenosis.7 At 2-year follow-up evaluations, these 2 treatments provided similar findings with respect to mortality rate, reduction in symptoms, and improved hemodynamic performance of the valve.7 However, TAVR is associated with significantly shorter stays in the intensive care unit and in the hospital,8 quicker improvement in quality of life,9 and less expense.10 Its future, therefore, seems bright. In fact, as newer, smaller, and safer prosthetic valves become available, and clinical experience with the transcatheter technique broadens, TAVR could someday become the standard of care for all patients with severe aortic stenosis.

Concluding Remarks

In all of the literature that I reviewed for this report, I found nothing about the specific composition of a TAVR team. To me, that is an important omission, because, like any other successful enterprise, a TAVR could never take place without the help and cooperation of a large group of dedicated and well-trained individuals. Aside from the personnel who participate in the procedure itself, many others function behind the scene. These are physician consultants, nurse practitioners, nurses, the study coordinator, administrative staff, office staff, various technicians, and numerous laboratory workers.

To every person on my TAVR team, I am most grateful. I am particularly indebted to the 2 interventional cardiologists who performed my TAVR; their incredible

talents speak volumes. And I will be ever-mindful of the divine blessings that have come my way.

Now that I have an efficient aortic valve, an improved coronary circulation, and a youthful outlook, I'm a new old man—86 years, targeting 90!

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