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Transcatheter Aortic Valve Replacement (TAVR) in Patients at Low-Risk for Surgical Aortic Valve Replacement (SAVR)

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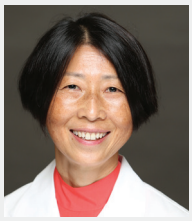
Transcatheter aortic valve replacement (TAVR) has been proven to be an effective therapeutic option for high-risk and inoperable/extreme-risk patients with severe, symptomatic aortic stenosis. Risk stratification and functional assessment, as well as the heart team's evaluation and recommendations, have become integral aspects of decision-making regarding surgical aortic valve replacement (SAVR) and TAVR. The Society of Thoracic Surgeons (STS) online database predicts mortality risk based on many patient factors such as age, ejection fraction and concomitant coronary artery disease. Greater than 8 percent risk of mortality is considered an extreme risk, while a mortality risk of less than 3 percent is considered a low risk. This calculation in conjunction with a frailty assessment and the multidisciplinary heart team evaluation have guided care for patients with aortic stenosis based on FDA indications for TAVR since approval in late 2011. Subsequently, TAVR has gained approval for patients deemed at intermediate risk (STS mortality risk 3–7 percent) with a frailty assessment and heart team decision for TAVR.

BayCare has participated in several of the major clinical trials that have led to TAVR's acceptance as the preferred treatment for most patients with severe aortic stenosis through our Center for Advanced Valve and Structural Heart Care at Morton Plant Hospital, including the recent Low-Risk for Surgical Aortic Valve Replacement Trial (LRT). This clinical trial was designed to compare and evaluate the effectiveness and outcomes of TAVR utilizing the Medtronic self-expandable transcatheter valve in patients at low risk (STS <3 percent) for surgical aortic valve replacement.

Patients at low risk for SAVR, as defined by STS risk and the multidisciplinary heart team's evaluation, were considered for enrollment in the investigational trial. Initially, candidates were randomized between TAVR and SAVR, but continued access protocols allowed the utilization of TAVR based on heart team assessment without randomization. The low-risk patient population with severe symptomatic aortic stenosis is different compared with intermediate and higher risk groups in that this group consists of younger, otherwise healthy patients, often with very active lifestyles. These patients lack features of high-risk patients such as prior heart surgery, COPD, renal failure, or other serious medical issues which may limit their life expectancy. Thus, the demands of TAVR in low-risk candidates raise new questions with regard to valve longevity, the hemodynamic profile of the valve and the value of reduced time until resuming a normal professional and personal lifestyle.

All TAVR valves are bioprosthetic (tissue) valves and have a limited durability similar to currently implanted surgical valves. Furthermore, the potential for complications associated with both TAVR and SAVR must be carefully considered in low-risk patients. These complications include stroke, leakage between the

Continued on page 2



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old diseased valve and the newly implanted valve (paravalvular leak), need for permanent pacemaker implant, renal impairment, and emergent conversion from TAVR to SAVR. TAVR and SAVR carry similar stroke risk (2–3 percent), although cerebral embolic protection devices are gaining favor for use during TAVR. The risk of postoperative permanent pacemaker requirement is higher with TAVR, 10–15 percent, compared to SAVR's 5–10 percent. Paravalvular leak, while initially a concern with TAVR, has largely been eliminated by advances in technology and CT scan-guided sizing. Perhaps most significant is the prospect of TAVR patients being discharged from the hospital on postoperative day 1, while SAVR patients remain in the hospital 4 to 5 days with possibly significant discomfort.

Determinants of the durability of bioprosthetic valves are patient age at implant, hemodynamic profile of the implanted valve and renal failure. Significant gains have been made in preoperative imaging which can help the heart team provide valuable advice regarding TAVR and SAVR sizing. This is quite important as many of these low-risk patients may ultimately require at least one subsequent valve replacement since they're likely to outlive their valve's durability. The durability of both TAVR and SAVR impact the long-term management of low-risk patients with co-existing coronary artery disease.

In anticipation of the FDA approval of TAVR, BayCare established the first adult structural heart center in the Tampa Bay region at Morton Plant Hospital in the fall of 2011, the Center for Advanced Valve and Structural Heart Care. The Morton Plant team reached the major milestone of performing their 1,000th TAVR procedure in the summer of 2018. BayCare opened another adult structural heart program on campus at St. Joseph's Hospital in 2014, and will open a third program at Winter Haven Hospital in Polk County, later this year. In addition to adult programs, BayCare is home to Tampa Bay's only comprehensive congenital heart disease (CHD) center, on the campus of St. Joseph's Children's Hospital. This unique program delivers a full spectrum of care for CHD patients from conception into late adulthood, and is a nationally recognized leader in both quality and volume of the transcatheter pulmonary valve implantation for CHD patients.

The programs utilize a multidisciplinary heart team that includes a heart team coordinator, cardiovascular surgeons, interventional cardiologists, echo/imaging cardiologists, cardiac anesthesiologists, advanced registered nurse practitioners, echo sonographers and a team of registered nurses. Clinical research staff are included in locations that are participating in clinical trials. The centers routinely interact and collaborate with a variety of other teams and programs including heart function clinics, radiology/CT imaging, critical care and the many other specialties involved in the care of these complex patients.

In addition to treating patients with "native" aortic valve disease, BayCare's structural heart teams also evaluate and treat patients with degenerative bioprosthetic aortic and mitral valves. These patients are treated by placing a new bioprosthetic stent-based valve inside their existing diseased valve using a transcatheter valve-in-valve (VIV) approach. Patients with paravalvular leaks in both the mitral and aortic positions, which occur around their surgical valves as a result of tissue deterioration, calcification or infection, are also treated in our centers. In addition to aortic valve replacement therapy, we were also the first in Tampa Bay to provide transcatheter mitral valve repair utilizing the MitraClip technique.

Through our program at Morton Plant Hospital, BayCare has been actively involved in many clinical trials during the past seven years, including the initial Partner II trial, a valve-in-valve trial, trials of new to market transcatheter valves, low-risk TAVR trials and investigations into cerebral protection devices that may reduce the occurrence of strokes. We're currently participating in the APOLLO trial, an investigational trial for transcatheter mitral valve replacement. Participation in clinical trials provides accessibility and innovative technologies for our patients with complex structural heart disease and enhances the ability for our medical community to provide innovative technology and excellent care for our patients.

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