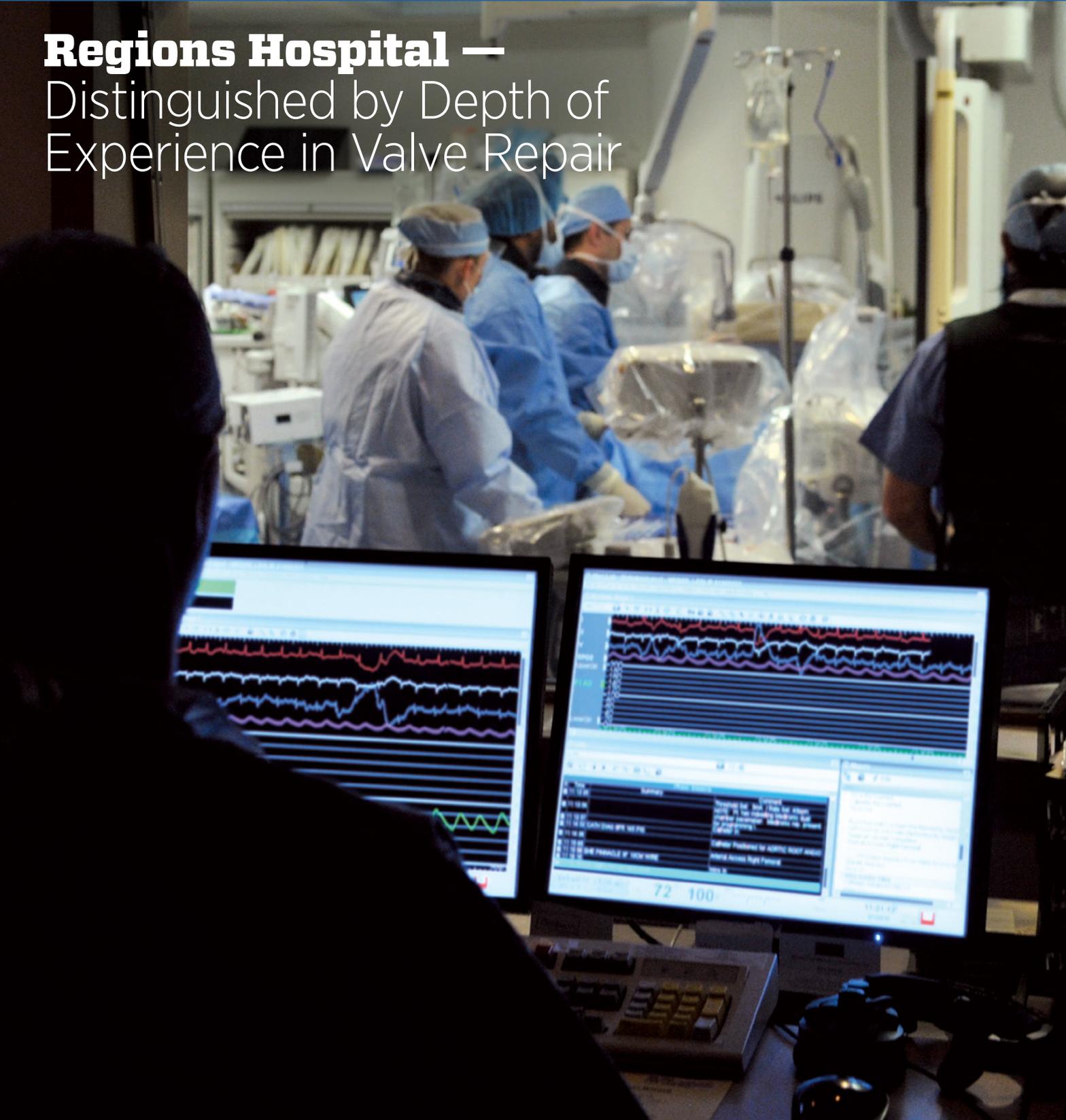


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Regions Hospital — Distinguished by Depth of Experience in Valve Repair





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By Marian Deegan

Johannes Brechtken, MD,
begins the process of TAVR
device insertion.

UNTIL RECENTLY, MEDICINE did not have much to offer cardiac patients such as Alice. At 83 years old, she suffered from aortic stenosis, complicated by severe Parkinson's disease and other medical issues that made traditional surgery too dangerous. The slow failure of her aortic valve rendered her debilitated, breathless and confined to her room.

Even the slowest walking pace left her gasping for breath.

Then in October 2012, the U.S. Food and Drug Administration (FDA) approved the Edwards SAPIEN heart valve for the treatment of severe symptomatic aortic stenosis in patients deemed unsuitable for surgery.

For patients such as Alice, the FDA's approval of the Edwards SAPIEN heart

valve offered much-needed hope. The transcatheter aortic valve replacement (TAVR) procedure delivers the valve via a catheter inserted into the body, usually through the femoral artery in the leg. Once positioned in the diseased aortic valve, the Edwards SAPIEN heart valve is expanded with a balloon and functions in place of the patient's failing valve.

Following FDA approval, Regions Hospital Heart Center, part of the HealthPartners Family of Care, was one of only three Minnesota sites — and the only site in Saint Paul — originally selected to offer the procedure. Because the TAVR procedure is complex, hospital applicants had to meet rigorous standards for approval. Heart programs were evaluated based on surgical and coronary intervention volumes, surgical quality and outcomes, and the expertise of surgeons in vascular and structural heart disease.

Comprehensive Care for Complex Patients

“Our heart program is distinguished by our experience with therapies, including catheter-based valve procedures, for a whole new category of patients who previously didn’t have many options,” explains Timothy Kroshus, MD, cardiovascular and thoracic surgeon at Regions Hospital Heart Center.

Regions Hospital Heart Center offers a complete surgical program that includes structural heart disease repairs, standard and minimally invasive valve repairs, and surgeries for congenital heart disease, arrhythmia and aneurysm. Additionally, the center offers comprehensive programs that monitor and follow patients through recovery. These extensive capabilities address the individual needs of each patient through a full range of state-of-the-art procedures.

Select Patient Screening Maximizes Outcomes

The FDA has approved use of the TAVR procedure for a select group of patients. During clinical trials for the TAVR procedure, only inoperable patients were eligible. The procedure improves survival rates for this patient population, even though current data indicates the risk of stroke and other complications is greater after a TAVR procedure than it is after conventional surgery. Because the procedure is so new, no long-term data exists to evaluate long-term patient outcomes or valve durability.

“If you compare a standard aortic valve replacement patient to a TAVR patient,

the standard surgery patient clearly does better,” explains Dr. Kroshus. “But we don’t offer TAVR to patients who are appropriate for standard surgery — we offer it to a carefully screened group of higher-risk patients. Approximately two-thirds of these inoperable or high-risk patients will not survive two years without a TAVR. For this very high-risk population, TAVR decreases the risk of dying by 20 percent.”

Regions Hospital Heart Center evaluates potential TAVR candidates using a Society of Thoracic Surgeons risk score and direct evaluation by several cardiologists and at least two surgeons. The center’s communication system is integrated so that primary care physicians, hospitalists and subspecialists share the same electronic health record. Evaluating physicians collect a complete picture of a patient’s condition and work collaboratively to identify the surgical, transcatheter or medical management solution that will maximize the patient’s outcome. These complex patients benefit from the full spectrum of resources that Regions Hospital is able to provide.

“We do a comprehensive analysis, and our heart team looks at the whole patient,” explains Stephen Smalley, MD, a cardiologist with Regions Hospital Heart Center. “We consider the referring physician and the patient as much a part of our team as our proceduralists.”

Cardiac Care at Level I Centers Minimizes Surgical Risks

Once a patient has been screened, evaluated and approved for TAVR, the procedure is performed by a team made up of 8–10 specialty physicians, including a cardiac surgeon, cardiologist and cardiac anesthesiologist.

“Results will be best if we properly select patients and treat them with a procedure that’s best tailored to their individual circumstances,” says Dr. Kroshus.

Because TAVR patients are medically delicate, it is critically important to have a well-trained surgical team to address potential complications. If a dangerous complication arises during the



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Rochus Voeller, MD, prepares to open the femoral artery access to place the TAVR device.

procedure, the team has the expertise to take care of the issue on the spot and without delay. Following surgery, the cardiovascular surgery ICU service manages patient recovery.

The heart team at Regions is distinguished by its depth of experience in valve repair. Members of the surgical team have performed thousands of valve interventions and aortic surgeries. The cardiac outcomes at Regions reflect the team’s expertise. In 2011, the Regions Hospital Heart Center’s mortality rate was zero, and Dr. Kroshus’ valve procedure mortality rate was zero in both 2011 and 2012.

“You have to be an expert in valve diseases and procedures to take on a new procedure such as TAVR,” explains Dr. Kroshus.

Enhanced Procedural Accuracy

The TAVR catheter can be threaded to the aortic valve through the femoral artery or through apical access. Going through the groin is much less invasive. Patients are up shortly afterward and are

able to go home in a day or two. The apical incision is associated with modestly more postoperative pain and morbidity, and a longer recovery time. For this reason, apical access is used only for patients whose vascular disease is so severe that transfemoral access isn't possible.

"Apical access is reserved for our vasculopathic patients — those whose arteries are filled with plaque and calcium," explains Dr. Kroshus. "These are sicker patients by definition. They have more limited long-term survival and higher risk of stroke and embolic complications."

"We are working with first-generation technology," adds Johannes Brechtken, MD, an interventional cardiologist with Regions Hospital Heart Center. "The catheter is almost a centimeter in circumference and usually requires a surgical cutdown to access the artery."

Dr. Brechtken anticipates that cut-downs will decrease by half in the next three to four years as subsequent generations of equipment become smaller, making the procedure more accessible for patients with smaller arteries.

Cardiac imaging guides the placement of the new valve and is a critical component of the procedure. Regions offers 3-D transesophageal echo imaging for appropriate valve cases. This imaging allows physicians to view the heart as a three-dimensional structure in real time, affording a better appreciation for the anatomy structure than traditional echo imaging.

"Imaging guidance is critical to achieving the best result," explains Dr. Smalley. "It accurately identifies the amount of valve leakage and shows whether the new valve is completely sealed."

Comprehensive TAVR Program Offers New Hope

As awareness of this procedure increases, Regions anticipates that it will be performing approximately 30 to 40 TAVR procedures each year. The heart team emphasizes that both its comprehensive care model and the expertise of team members are critical for maximizing patient outcomes.

"We have the most comprehensive surgical program in the Twin Cities in terms of our interactions and collaborations with cardiology, our surgical program, our dedicated cardiac surgical intensive care units, and our dedicated endocrine service for heart surgery patients with postoperative diabetes," says Dr. Kroshus.

Hospitalists at Regions Hospital manage the medical issues of each heart surgery patient through discharge planning, social work and clinic follow-up. Hospital administration has made it a priority to integrate all program services from the patient's initial evaluation through postoperative recovery and follow-up. Regions Hospital Heart Center conducts monthly evaluations for markers of care and mortality. Physicians gather to present and evaluate the complications of each case.

"Our evaluations show us what we need to tweak to maintain the highest level of care," says Dr. Kroshus. "We want to take good performance and make it great performance. That requires constant feedback and learning. Our open discussions are vital to maximize outcomes."

"The TAVR procedure enables us to give our patients an option they didn't have three years ago," says Dr. Smalley. "It is really miraculous to see the old valve pushed out of the way by a new, functioning valve."

Without treatment, the projected outcomes for high-risk and inoperable patients with aortic stenosis are grim. For patients such as Alice, the TAVR procedure offers a new option and new hope. Alice recently sent her cardiologists a photo of herself walking her dogs.

"She looks so happy," says Dr. Brechtken with a smile. "Today, Alice is enjoying a quality of life that would have been unimaginable without this procedure. It is exciting to be able to help these patients. For me, outcomes like Alice's are what make our work so worthwhile."

For more information about Regions Hospital Heart Center, visit www.regionshospital.com/heart or call 651-254-4887. ■



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