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Minneapolis Heart Institute Valve Center at Abbott Northwestern Hospital

*Multidisciplinary Approach to
Complex Treatments in Valve Disease*

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Multidisciplinary Approach to Complex Treatments in Valve Disease

VALVE ABNORMALITIES THAT cause aortic stenosis and mitral insufficiency predominantly affect our growing elderly population. In the United States, an estimated 140,000 patients suffer severe aortic stenosis annually. When aged in our 80s, 5% to 7% of us will develop severe stenosis. By the time we reach our 90s, 10% to 12% of us will become afflicted with this disease. Mitral insufficiency is even more common.

Currently in the United States, conventional surgical valve repair and replacement are the only treatment options. Elderly patients with comorbidities or excessive frailty are at greater risk for these invasive treatments. Medications have minimal effect on symptoms, and unlike surgery, they don't change the natural history of the disease. Without invasive treatment options, these patients

face a painful decline in quality of life, reduced longevity and heart failure.

At the Minneapolis Heart Institute (MHI) Valve Center at Abbott Northwestern Hospital, a multidisciplinary, subspecialty team — led by Director Wes Pedersen, M.D., and Co-Directors Vib Kshetry, M.D., and Kevin Harris, M.D. — has been pioneering percutaneous treatment research to address both aortic stenosis and mitral insufficiency. These physicians represent the subspecialties of interventional cardiology, cardiac surgery and echocardiography, respectively. In 2008, Dr. Pedersen performed the world's first in-man percutaneous implant of the iCoapsys mitral valve device to repair functional mitral insufficiency.

“Between 30% and, possibly, 50% of people in the United States are not receiving treatment for aortic stenosis because

they are either frail or have comorbidities that place them in an excessively high-risk group for surgery,” explains Dr. Pedersen. “Fewer than half of the 150,000–250,000 patients with significant mitral insufficiency are undergoing surgical repair or replacement. The large, remaining group is comprised of patients who are not traditional valve surgery candidates for similar reasons: comorbidities, frailty or end-stage left ventricular dysfunction. We need a less invasive way to treat these patients. Percutaneous or transcatheter options were developed specifically for those patients in whom surgery is not an option. In Europe, 14% of the aortic valve replacements being carried out are transcatheter. That number is expected to rise to 20% next year and possibly to 40% in the next three to four years.”

The MHI Valve Center is one of 27 centers participating in the PARTNER



A multidisciplinary team of providers meets weekly to discuss complex valve cases.

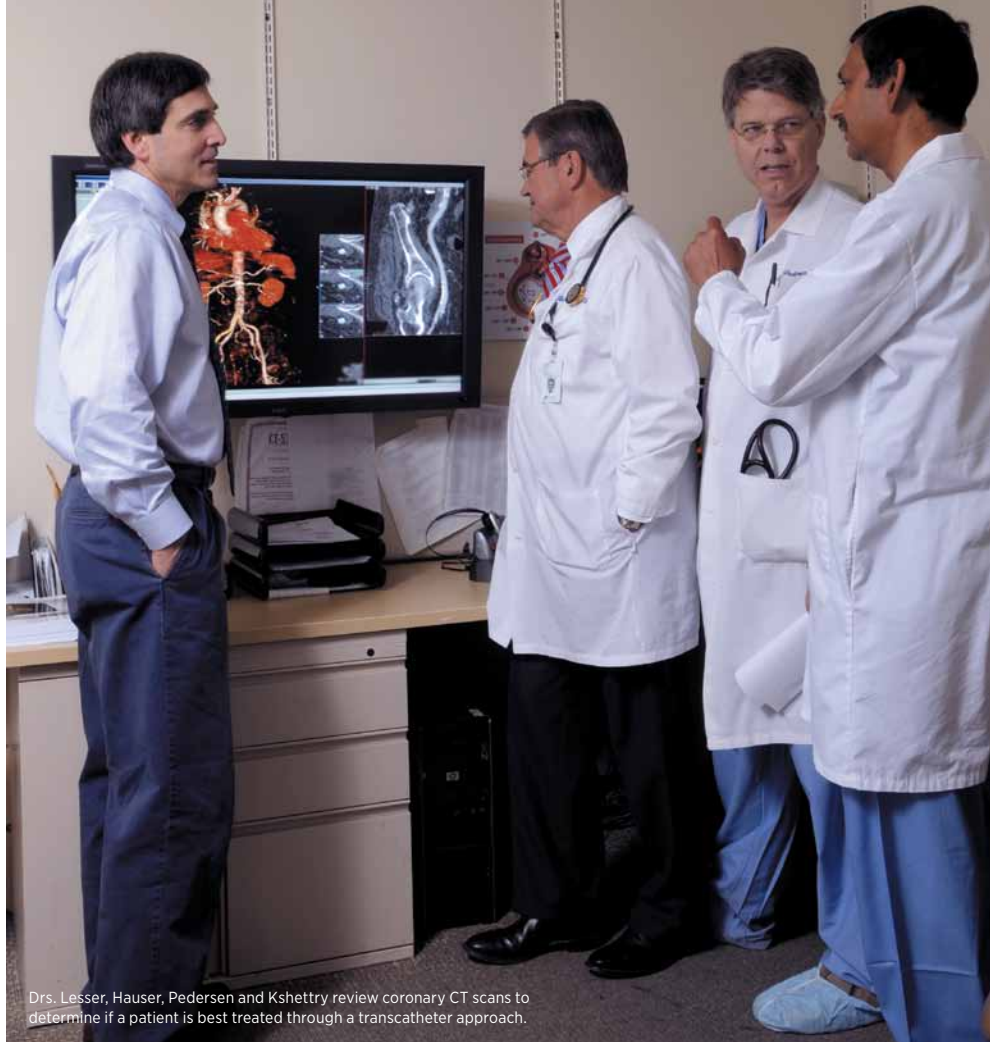
II Trial to evaluate transcatheter aortic valve implantation (TAVI) using the Edwards SAPIEN XT balloon expandable valve in aortic stenosis patients who are refused conventional surgery.

“In the PARTNER I Trial, the patients were very sick,” explains Dr. Pedersen. “For those patients randomized to medical therapy without the device, there was 50% mortality at one year. Even in the group receiving the device, there was a 30% mortality at one year. These mortality statistics are worse than most cancers. Nevertheless, with the device, there was a profound 20% absolute decrease in mortality. The PARTNER I study data also demonstrated dramatic improvement in quality of life by almost all measures, an extremely important point in very elderly patients.

“It’s been a long time since we’ve seen randomized data that made such a huge difference,” notes Dr. Pedersen. “For every five patients treated, one life was saved. This is remarkable when you consider that, typically, we treat 30 to 100 people to save one life. On average, the transcatheter valve increased lifespan by 1.9 years. If you give a 90-year-old patient another two years of life with significantly enhanced quality, I think that’s pretty good. But more importantly, the patient does.”

The Edwards SAPIEN XT valve has received panel approval. Presuming the U.S. Food and Drug Administration (FDA) follows suit and rules in favor of approval in October, this transformational therapy will be on the market and available for use. It is anticipated, however, that its use will be restricted to nonsurgical candidates. The MHI Valve Center is currently evaluating patients for participation in PARTNER II. The trial requires patients have an estimated combined perioperative mortality and major morbidity of greater than 50%.

The center also has extensive experience in performing transcatheter balloon aortic valvuloplasty (BAV), which provides significant symptom palliation for aortic stenosis patients who are poor surgical candidates and do not qualify



Drs. Lesser, Hauser, Pedersen and Kshetry review coronary CT scans to determine if a patient is best treated through a transcatheter approach.

for participation in the PARTNER Trial. Although restenosis is reported in 42% to 83% of these patients at six to 12 months, they can safely be redilated to extend the durability of quality of life enhancement. “This is not a definitive procedure, but it fairly safely takes most patients from NYHA [New York Heart Association] functional class 4 to functional class 1 to 2,” notes Dr. Pedersen. “It works well, and the risk is low — a 1% to 2% risk of mortality and a 1.5% risk of stroke. We do 80 to 100 of these procedures a year. Patients are generally out of the hospital in one to three days, and they feel much better. BAV also improves the probability that these patients will continue to function independently.”

The MHI Valve Center participated in the EVEREST II Trial, evaluating the use of the MitraClip, a percutaneous valve repair technique, to address mitral insufficiency. Unlike the PARTNER studies, this research was not restricted to high-risk patients. Any patient with a qualifying mitral valve abnormality who

was willing to be randomized to the mitral clip or surgical repair was able to participate.

“Of all patients with severe mitral insufficiency, mitral clip therapy may be appropriate for 25%,” explains Dr. Pedersen. “The dominant jet of mitral sufficiency must originate from the P2 facet, or central portion, of the posterior valve leaflet. Although surgical repair is excellent and the preferred therapy for degenerative mitral regurgitation (MR), we are starting to realize that surgical repair may not be the gold standard for patients with functional mitral regurgitation. Functional MR is a ventricular disease resulting from left ventricular dysfunction. Although it hasn’t been proven yet, the clip may be the better option for some patients in this group, especially those at high surgical risk.”

Seventy-two percent of patients repaired with the mitral clip had a successful outcome at one year compared with 88% of the surgically treated group in the randomized EVEREST II Trial. “This is very positive,

in light of this procedure's safety and its proven benefit in high-risk patients poorly suited for surgery," explains Dr. Pedersen. "What makes this procedure attractive is the ability to place, but not initially release, the clip across the regurgitant valve orifice via a percutaneous catheter under transesophageal echo guidance. After initial clip placement, the echocardiographer and operator determine the adequacy of mitral regurgitation reduction. If the clip fails, in spite of testing multiple sites, it is not deployed, and the patient can be referred for elective surgical repair."

"Three-dimensional, echocardiographic imaging has given us much more precise information of the catheter's position with respect to the mitral valve," states Dr. Richard Bae, Director of Interventional Echocardiography. "It is useful in reducing the procedure time of these often lengthy cases. This offers a rationale for attempting the less invasive clip first. Again, my colleagues and I are not convinced that the clip is an equivalent first option for degenerative valves such as mitral valve prolapse, but see it playing a more significant role in functional mitral regurgitation, especially for those at higher surgical risk. I think that the use of the clip will grow significantly following FDA approval. We are currently screening for these patients in an open-access, FDA-approved registry."

"We have also begun percutaneously closing paravalvular leaks," explains Dr. Pedersen. "Between 1% and 3% of surgical valves develop a leak on the periphery of the artificial valve. If the leak results in heart failure or hemolytic anemia, the standard of care is to surgically replace the valve.

"This initial valve failure, however, is often caused by poor tissue milieu that will result in a 10% to 15% paravalvular leak recurrence following a second operation," Dr. Pedersen continues. "In addition, any repeat surgery carries a higher operative mortality. We use metallic mesh devices to plug these holes via transcatheter delivery systems, which have reported success rates of 70% to 80%. The structural complexity of these novel transcatheter procedures requires the combined expertise of a multidisciplinary cardiac interventional team



that includes advanced imaging experts.

"The center is a truly multidisciplinary team. Currently, TAVI procedures are carried out in the presence of two interventional cardiologists, two cardiac surgeons, an interventional echocardiographer, an anesthesiologist and an on-call vascular surgeon, in addition to circulating nurses and scrub techs."

"We foresee regional valve centers of excellence arising that will be the most qualified and have the resources available to perform these technically demanding, complex valve procedures to ensure safe and effective outcomes," stresses Dr. Kshetry.

"Preoperative advanced imaging and intraprocedural transesophageal echo with 3-D capability are essential," states Dr. Harris. "Our imaging subspecialists understand the structural complexities of these diseases. Their presence is necessary on the day of surgery to guide the surgeon through the procedure."

At the MHI Valve Center, the team of surgeons and interventional, echo, CT and MRI imaging specialists meet weekly to discuss complex aortic valve cases for final approval. The group evaluates whether a patient is a reasonable risk for surgery or a better candidate for the transcatheter approach. A formal presentation of candidates deemed appropriate for participation in the PARTNER II TAVI Trial is assembled and presented to a national forum twice weekly.

Each week, the center receives five to

PARTNER II TRIAL CANDIDATES

- THE MHI VALVE** Center welcomes qualified candidates to participate in transcatheter research studies. Some of the relevant criteria for participation in the PARTNER II Trial include:
- + a combined morbidity mortality risk of 50%, assessed by two surgeons and a cardiologist
 - + echocardiographic aortic valve parameters that include:
 - a 40 mm or greater mean gradient
 - a peak velocity of 4.0 meters per second or greater
 - a valve area of less than 0.8 cm² or valve index of <0.5 cm² /m²
 - iliofemoral arteries that are 7 mm or greater
 - a left ventricular ejection fraction of greater than 20%
 - bicuspid valves are excluded

Physicians are invited to contact the MHI Valve Center at (612) 863-VALV (8258).

10 referrals for potential participation in the PARTNER II Trial. Of those, one to two will qualify.

"The most common reason for being disqualified from the transfemoral delivery approach is severe disease in the iliofemoral arteries, which prevents delivery of these large catheters to the heart," says John Lesser, M.D., Director of Cardiovascular CT and MRI. "We are meticulous in our measurements of these arteries before approving patients to undergo TAVI."

"Many of us believe that in 10 years, if longer term follow-up demonstrates equivalent valve durability, these transcatheter procedures may become the treatment of choice," says Dr. Pedersen. "We see an opportunity with transcatheter procedures to offer a substantial percentage of high-risk patients an alternative treatment that has the potential to enhance their quality of life." ■