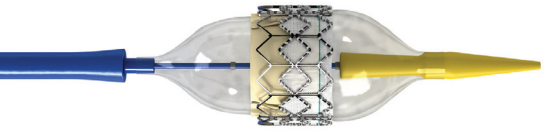
FOR PHYSICIANS

CARDIAC MONITOR

Summer 2015 / dignityhealth.org/heartandvascular

Dignity Health Leads the Way in Minimally Invasive Treatments



Over the past ten years, emerging technology and ongoing research have revolutionized cardiac surgery. Procedures that previously involved sternotomy, lengthy recovery and myriad complication risks have been replaced with minimally invasive procedures – offering quicker recovery, less risk, and less trauma to the body.

Dignity Health Heart and Vascular Institute has been a part of this revolution from the beginning. Surgeons at Mercy General Hospital were among the first in Northern California to use a robotic surgical system for valve repairs. And now, the Institute's TAVR (Transcatheter Aortic Valve Replacement) program has successfully replaced aortic valves in hundreds of patients – without opening their chest. "The TAVR program continues to offer cutting-edge care and technology. By being the only research center in our region in the PARTNER II trial, a wider patient population has access to newer technology not available at all sites," says Doris Frazier, Vice President, Dignity Health Heart and Vascular Institute. [*See Research article, page 3.*]

Robotic-assisted surgical systems have forever changed minimally invasive surgical procedures. Dignity Health Heart and Vascular Institute remains one of the few cardiac surgical teams in Northern California to offer mitral valve surgery and other cardiac surgical specialty procedures using a robotic platform.

Robotic-Assisted Surgery Offers Big Benefits

By utilizing the da Vinci Si HD Surgical System, Dignity Health surgeons are able to get a clear, 3-dimensional, high definition view of areas of the heart previously inaccessible during traditional, open-chest mitral valve procedures. The surgeon's hands control the movement and placement of the instruments, which are attached

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Valve Disease Affects Millions of Americans

More than 5 million Americans are diagnosed with some form of valve disease every year, according to the American Heart Association.

Approximately 1.5 million people in the US suffer from aortic stenosis – the most common heart valve condition. In aortic stenosis, the aortic valve narrows, restricting blood flow to the entire body. Once a patient begins to display symptoms, their survival rate is estimated to be 50% at two years and 20% at five years if the valve is not replaced.

Patients are generally asymptomatic until the narrowing of the valve is quite progressed. Symptoms can include:

- Shortness of breath (with exertion)
- Fatigue (with increased activity)
- Chest pain (angina) or chest tightness
- Feeling faint or fainting upon exertion
- Heart palpitations/murmur

Because aortic valve stenosis weakens the heart muscle, in its advanced stages it can lead to heart failure. Signs of heart failure include worsening fatigue, shortness of breath, and swelling in the ankles and feet.

Treatment for aortic valve stenosis may begin with medication for more mild cases. However, the only "cure" is a corrective procedure, which is considered once symptoms develop and narrowing is severe.

Dignity Health
Heart and Vascular Institute
of Greater Sacramento

CARDIAC MONITOR

Referral Criteria for TAVR

For now, the FDA has limited use of Transcatheter Aortic Valve Replacement (TAVR) to patients who are:

- Diagnosed with severe calcific aortic stenosis of the native aortic valve or severe stenosis of a bioprosthetic aortic valve.
- And who are at high risk for traditional open valve replacement or are considered inoperable.

Severe aortic stenosis is demonstrated by:

- AVA <1.0 cm2
- Mean AV gradient > 40 mmHG

AND/OR

- Peak AVA Velocity > 4 m/sec

To refer a patient to Dignity Health Heart and Vascular Institute's TAVR team, please call 877.999.8287 or 916.453.4768.

Research News: PARTNER II Clinical Trial

By Sarah Bordash, RN, BSN

Dignity Heart and Vascular Institute has been participating in the Partner II Clinical Trial sponsored by Edwards Lifesciences for the past two years. The purpose of this research study is to evaluate the Sapien XT™ and Sapien 3 transcatheter heart valves (THV) in patients with severe, symptomatic aortic stenosis.

The Sapien XT™ THV has been FDA-approved since the spring of 2014 and the Sapien 3 THV received FDA approval on June 17.

Mercy General Hospital was the only hospital in the Sacramento area that participated in the research trial evaluating the Sapien 3 valve.

Currently these valves are only approved for patients who are considered inoperable or are considered high risk for surgery. The Partner II trial offered this technology to patients who are considered "intermediate risk" for surgery (STS score 4-8).

All patients enrolled in the Partner II Clinical Trial are followed for five years.

Increased Risk of Type 2 Diabetes With Statin Treatment

By James Palmieri, Pharm.D.

A recently published population-based Finnish study[1] increases the concern for new onset Type 2 diabetes in statin-treated patients. This study followed 8,749 non-diabetic men over an average of 5.9 years and showed a 46% increase in Type 2 Diabetes diagnosis in the statin-treated men.

The study is limited by the fact that no women, and only Northern European Caucasian men were included in the study. This is significant since the development of diabetes varies by ethnicity. Also, the majority of patients were treated either with simvastatin and atorvastatin. The results were not powerful enough to extrapolate to less frequently used statins, though at this time this is widely regarded to be a class effect.

Both decreased insulin sensitivity and insulin secretion were attributed as the cause for diabetes in these patients, and the affect appears to be dose-dependent. This is particularly important in light of the recently published guidelines[2] which advocate high, or moderately-high doses of statins be used to treat most patients at risk for cardiovascular events. It is unclear whether the effect is reversible.

Controversy regarding the latest guidelines persists, most notably in the calculator used to determine risk, but also to the shift to dose-based statin therapy as the only medication therapy recommended. However, the guidelines do encourage individualizing risk management, and discussing the risks and benefits with each patient prior to deciding on a treatment plan for that risk.

In many patients, the risk for a cardiovascular event outweighs that of developing diabetes. However, in some patient populations - such as obese patients and others with a strong family history of developing type 2 diabetes - it is prudent to exercise caution. Lowering the dose of statin, with or without adding additional medications with demonstrated benefit such as ezetemibe, may be a sound strategy in select patients at greatest risk.

References:
[1] *Cederberg H, Stancakova A, Yaluri N, et al. Increased Risk of Diabetes with Statin Treatment is Associated with Impaired Insulin Sensitivity and Insulin Secretion: A 6 Year Follow-up Study of the METSIM Cohort. Diabetologia 2015;58(5):1109-17*
[2] *Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation 2014;129:S1-45*

Minimally Invasive *(continued from first page)*

to robotic arms. Those robotic arms mimic the function of the surgeon's hand, allowing the surgeon to follow the same steps as a traditional mitral valve surgery.

The robotic-assisted system is particularly beneficial for delicate procedures including mitral valve repair; atrial septal closure; surgical treatment of atrial fibrillation; and removal of tumors from the heart. The exceptional level of precision provided by the system translates to real benefits for the patient, including:

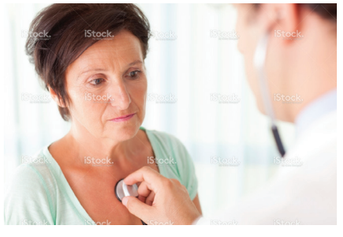
- Quicker recovery (2-3 weeks vs. 2-3 months for opens surgical repair)
- Reduced risk of infection
- Shorter hospital stay
- Less blood loss, pain and scarring

Mercy General Hospital has performed more than 150 robotic-assisted procedures, more than any other provider in the region. The robotic-assisted team at Dignity Health also was the first to graduate from the International College of Robotic Surgery (ICRS), completing a yearlong fellowship sponsored by St. Joseph's Hospital in Atlanta.

Replacing Aortic Valves Without Opening the Chest

In addition to repairing faulty valves minimally invasively, Dignity Health Heart and Vascular Institute is among the select providers in the nation offering patients catheter-based valve replacement as well, using Transcatheter Aortic Valve Replacement (TAVR). More than 220 patients have benefited from this life-saving technology provided at Mercy General Hospital.

In TAVR, the replacement valve is placed on a catheter that is inserted into the body and advanced into the heart for implantation. All TAVR procedures are performed in a hybrid surgical suite, which provides advanced imaging technology in a surgical environment, allowing physicians to address patient needs quickly. TAVR offers a faster recovery time, less pain, and better quality of life after the procedure.



TAVR is currently FDA- approved for patients suffering from aortic valve stenosis who are considered high risk or not candidates for open heart surgery (due to medical history, age or current condition). [*See Referral, page 2.*] Without treatment, half these patients will die within a year of the onset of symptoms. And via clinical trials like PARTNER II, lower risk patients may be eligible for TAVR and have access to the newest valve designs not commercially available at other sites.

In time, it is expected that the FDA will broaden the indications for TAVR to include a wider spectrum of patients.

Save the Date: Education Opportunities

Dignity Health Heart and Vascular Institute is proud to host the following Continuing Education events for providers.

Vascular Disease Conference

Thursday, Aug. 20
5:30 – 8:30 p.m.
Hilton Sacramento Arden West Hotel

Register at DignityHealth.org/SacVascularCME.

Topics will include minimally invasive heart surgery, management of abdominal aortic aneurysm, and vascular health risk factor modification.

Cardiology & Electrophysiology Symposium: Concepts & Controversies

Saturday, Oct. 3
7 a.m. – 4:30 p.m.
Hyatt Regency Sacramento

Register at DignityHealth.org/SacCardiologySymposium.

Topics will include the value of remote monitoring; cardiac imaging updates; genetic testing for cardiovascular disease; transcatheter valve therapies; and coronary and peripheral interventions.

Upcoming Community Events

Dignity Health Heart and Vascular Institute is proud to participate in several community outreach health education events throughout the year. Please share the following information with your patients and encourage them to attend. Of course, we'd love to see you there as well!

Heart Walk

Join us at the American Heart Association Heart Walk on Saturday, Sept. 26 at William Land Park in Sacramento. Play games, have fun and learn valuable tips about improving your heart health! Watch for details at DignityHealth.org/HeartandVascular.

Care Begins With Me

This annual event is the ultimate ladies night out! Be treated to great food, an inspiring guest speaker and care chats that focus on health topics important to you. It's all happening on Thursday, Oct. 1 at the Sheraton Grand in Sacramento. Register at CareBeginsWithMe.org.

Referral Resources

The following heart disease management programs are available through physician referral.

CHAMP®	916.564.2880
Cardiac Rehabilitation	
Mercy General Hospital	916.453.4521
Mercy San Juan	916.537.5296
Sierra Nevada Memorial Hospital	530.274.6103
Pulmonary Rehabilitation/Smoking Cessation	
Mercy General Hospital	916.453.4268
Mercy San Juan	916.537.5299
Sierra Nevada Memorial Hospital	530.274.6084
ICD and Cardiac Support Group	916.453.4521
HeartCaring	916.733.6245
Adv. Heart Disease Clinic	916.453.4768

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