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healthpoints

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Message from the Chief



Emile Bacha, MD

Message from the Chief

At NewYork-Presbyterian/Columbia we continue to be leaders in basic and clinical research, discovering new and better ways to treat heart disease. Over the past two decades, we've made extraordinary progress in helping children with congenital heart defects. Survival rates have steadily increased and now many children who had surgery to correct these defects are in their 20s. Our multidisciplinary team at the Schneeweiss Adult Congenital Heart Center (CHD) has launched several important studies to learn more about the medical needs of this generation. High on our list is determining which of these patients may need follow-up surgeries as adults to further extend their lifespan and increase their quality of life.

In the last issue of *healthpoints*, we looked at new procedures to repair aortic aneurysms, address aortic and mitral valve disease, and reduce the symptoms of hypertrophic cardiomyopathy. In this issue, we continue reporting on these advances, highlighting our latest, and most exciting, clinical research. Below, you'll learn more about new catheter-based approaches to valve disease that offer low-risk, low-impact solutions to serious valve conditions. Please feel free to call us with any questions or to find out how you can enroll in any of these important studies.

Warmly,

Emile Bacha, MD

Chief, Division of Cardiac, Thoracic, and Vascular Surgery

Adult Congenital Heart Disease: Meeting the next generation of challenges



Marlon Rosenbaum, MD

Babies born with heart defects are now more likely to be successfully treated and grow into healthy adults. Yet this has created a new set of challenges: how to care for the first-generation who had childhood surgeries for congenital heart disease.

These patients face problems that simply were not anticipated when they received treatment decades ago, says **Dr. Marlon Rosenbaum**, *Director of the Schneeweiss Adult Congenital Heart Disease Center at NYP/Columbia.*

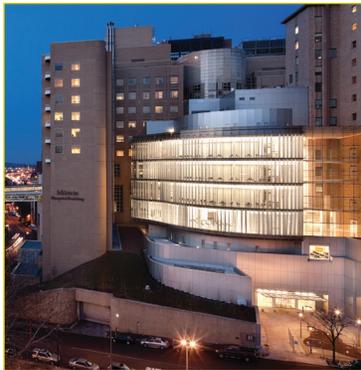
The center treats approximately 3,000 adults every year, enough volume to observe the problems that arise in this unique population. Dr. Rosenbaum's team is now studying patients who had early surgery for Tetralogy of Fallot to determine if and when they should have

Adult Congenital Heart Disease ~ Continued on page 4

Repairing Heart Valves without Surgery

The Structural Heart and Valve Center at NYP/Columbia has long been a leader in catheter-based treatment—the least invasive therapy—to repair the mitral valve. This valve regulates blood flow between the upper and the lower chambers on the left side of the heart. When it is damaged or defective, blood flows back up into the upper chamber, producing Mitral Regurgitation (MR).

Patients with MR often have a heart murmur (a turbulent or whooshing sound picked up by a stethoscope) and may suffer from heart palpitations, shortness of breath, fatigue after exertion, and swelling in the feet or ankles. As their valve disease progresses, they may experience other problems including heart failure, a condition in which the heart can't pump enough blood to meet the body's needs.



The Vivian and Seymour Milstein Family Heart Center

Because our volume is one of the highest in the country, our Center is one of the first to study and test new devices for heart valve repair and replacement. As a result, our patients benefit from the latest therapies.

The following clinical trials promise to extend our range of options for patients not fit enough to undergo the rigors of conventional surgery. These catheter-based approaches are also referred to as “percutaneous” (meaning “performed through the skin”) since no surgical incisions are necessary. Another advantage: The

patient doesn't have to be placed upon a heart-lung machine during these procedures. Because the following treatments are minimally invasive, they are generally associated with a significantly faster recovery time and a lower overall risk.

The COAPT Trial: More Data on the MitraClip

This major multi-center trial will evaluate the MitraClip, the first catheter-based treatment for patients with MR whose valves leak due to depressed heart function. The MitraClip was patented by physicians at NYP/Columbia. A clip is mounted on the end of a catheter then threaded through a vein in the groin into the right atrium. The clip is opened (its ends parting like the two legs of a clothespin) as it passes through the mitral valve. When the heart contracts, the ends of the clip grab onto the flaps



Chest radiograph showing two MitraClips projecting over the heart

of the valve. The clip is then moved into the “closed” position, pinning the flaps together. The result is a bow-tie-shaped opening that permits blood flow when the heart relaxes, but prevents any leakage or back flow, when the heart contracts.

The COAPT trial will help determine the best way to manage patients with moderate to severe functional MR. If the trial shows benefits with the MitraClip, many more patients may soon be eligible to receive this effective therapy.

The GDS Accucinch: An Adjustable Solution

A second trial will focus on the GDS Accucinch System—another new transcatheter approach to mitral valve repair. This device was designed to reduce congestive heart failure in MR patients who aren't healthy enough for surgery. Placed through an artery in the patient's groin, it cinches the mitral annulus—a ring shaped structure that anchors the mitral valve and separates the top and bottom chambers on the left side of the heart. Cinching the mitral annulus helps

increase contact between the mitral valve leaflets and stems the backward flow of blood through the mitral valve.

According to the study leader, **Dr. Martin Leon**, “With the GDS Accucinch System, we can properly size the mitral opening by measuring MR in the beating heart.” These are adjustments that cannot be made while the patient is on a heart-lung machine during traditional open surgery.

The Neochord System: Artificial Muscles Support the Valve

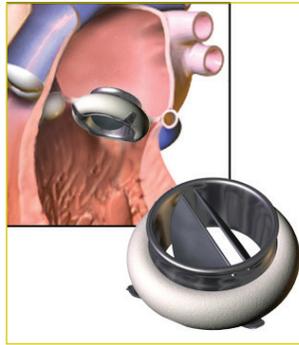
The Neochord System uses artificial muscles to repair this defect. These cords can be applied without the use of a heart-lung machine. They are placed on the diseased portion of the mitral valve through a small incision in the chest. A national trial of this device will begin in early 2017, and will

be led by **Dr. Michael Borger**, *Director of the Cardiovascular Institute*. “The Neochord System has been used in Europe in many hundreds of patients with good results,” says Dr. Borger. “This exciting technology will soon be available in America for patients with a prolapsed or abnormal mitral leaflet and MR.”

Advances in Mitral Valve Replacement

Mitral valve repair has long been considered preferable to replacement because the valve is intimately connected to the functional anatomy of the left ventricle. However, when repair can't be performed successfully mitral valve replacement is an option.

The techniques of transcatheter mitral valve replacement (TMVR) are still evolving and we currently have several trials underway to evaluate the safety and feasibility of this approach. These studies will help us to answer the following:



Rendering of Mechanical Valve

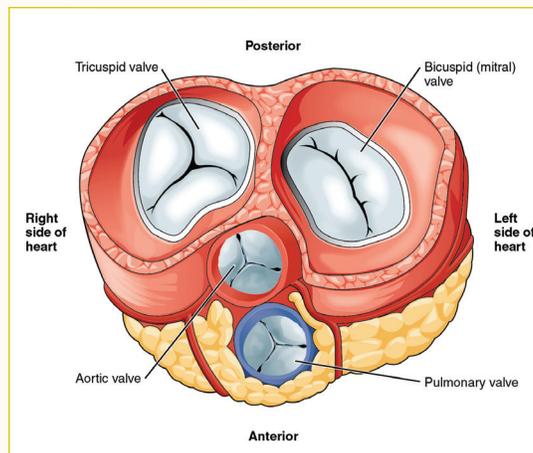
- What forms of valve disease are best treated with TMVR?
- How safe is TMVR?
- How much valve leakage occurs after TMVR?
- After TMVR, is there any recurrence of mitral valve regurgitation over time, and if so, how much?
- Is TMVR equal or superior to surgery? Equal or superior to MitraClip?

New Repairs for the Tricuspid Valve

Tricuspid valve regurgitation (TR) isn't as common as MR. Yet patients with this condition have a similar problem with valve leakage or backflow. The tricuspid valve has three leaflets that control the movement of blood between the upper chamber (atrium) and lower chamber (ventricle) on the right side of the heart. When these leaflets fail to close all the way, blood moves backwards into the ventricle.

As in patients with MR, the heart has to pump harder to move blood through the body when TR is present. TR has been traditionally addressed with open surgery, but many patients with severe TR have risk factors for an open procedure. Now there is new hope on the horizon for a less invasive approach.

Dr. Rebecca Hahn of The Valve Center is leading a national trial of TriAlign, a catheter-based device for repair of the tricuspid valve. A suture with a small wad of material is



A damaged tricuspid valve (upper left) can leak, causing blood to flow back into the ventricle.

used to cinch the valve, making the leaflets close more fully—and thereby reducing the leak.

Dr. Hahn says, “We are extremely excited to be pioneering an innovative repair for the tricuspid valve. Until now, surgery to replace the tricuspid valve has been associated with a significant mortality rate. This new, less invasive approach is a welcome advancement.”

Dr. Susheel Kodali, Director of the Structural Heart and Valve Center, is testing the Edwards FORMA transcatheter valve system—another

minimally invasive way to repair the tricuspid valve. Using a catheter, physicians place a foam-filled polymer balloon “filler” in the area of the leakage. The patient’s leaflets grab onto the balloon and this reduces regurgitation. ■

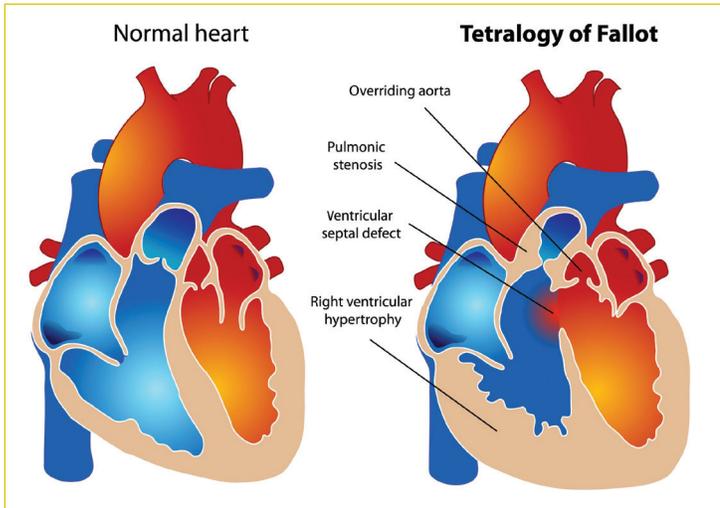
For more information about clinical trials for valve repair and replacements, please contact the Structural Heart and Valve Center at 212.342.0444.

Upcoming Patient Awareness Days

November 5, 2016 **Pancreatic Cancer Awareness Day.** This program features medical experts on pancreatic cancer prevention and genetics along with patient stories.

January 13, 2017 **Weight and Metabolism Awareness Day.** The COMMiT program will explore nutrition, mindful eating, medical weight management, and endoscopic and surgical options.

Register for these events at www.ColumbiaSurgery.org/events.



replacement of their pulmonary valves, as adults. Tetralogy of Fallot is a constellation of heart defects that permits oxygen-poor blood to flow through the body.

“Tetralogy of Fallot patients underwent surgery to relieve obstruction of blood flow to the lungs,” says Dr. Rosenbaum. “We now know that a leak in the pulmonary valve created during the repair causes significant enlargement of the right ventricle over time. But no one is really sure when to replace the pulmonary valves in these patients. We have been looking at data from cardiac MRI, exercise testing, and quality of life assessment to get a better understanding of when to do this surgery. We are also seeing similar issues in patients who underwent repair of pulmonary stenosis during childhood.”

Some patients with congenital heart disease have hypertrophic cardiomyopathy (HCM) which causes the heart muscle to thicken and have difficulty contracting. Dr. Jonathan Ginns, Medical Director of the Hypertrophic Cardiomyopathy Program and a senior member of the Adult Congenital Heart Disease Center, treats many adult patients with HCM. He is involved with a number of studies identifying novel treatments for these patients through collaboration with surgeons, imaging specialists, and experts in heart failure, genetics, and pediatrics.

“We have entered a new phase in the care of adults with congenital heart disease,” says Dr. Rosenbaum. “The first two decades of surgical repair demonstrated to us that adult survival was possible. Now we are conducting multi-center research to help us refine management that will improve longevity.”

Recently, the Adult Congenital Heart Disease program recruited **Dr. Matthew Lewis** to promote cutting edge research and continue providing patients with the most advanced care available in this country. Dr. Lewis has a personalized medicine grant and is a valuable addition to our team.

To serve the growing population of Adults with Congenital Heart Disease, we have added practice locations at the Tully Health Center in Stamford, CT, at the Vizza Pavilion in Roslyn, Long Island, and downtown Brooklyn. ■

To learn more or to schedule an appointment, please call 212.305.6936.

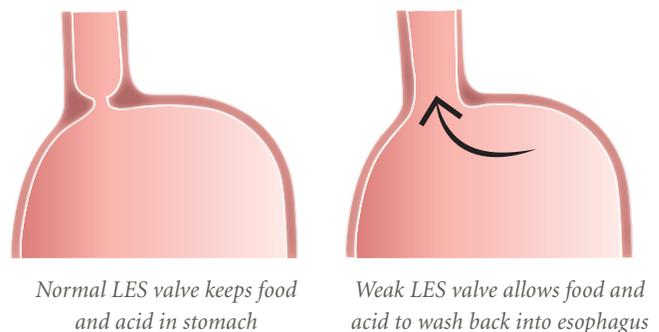
New Clinical Trial for Severe GERD

GERD (gastroesophageal reflux disease) now affects nearly 65 million Americans. Also called acid reflux or heartburn, GERD occurs when stomach contents back up into the esophagus. Untreated, it can lead to Barrett’s esophagus, a dangerous precancerous condition. Most people with GERD can be effectively treated using acid-blocking medication, but nearly a third continue to have symptoms.

The *LESS GERD trial* will examine the effectiveness of the EndoStim Lower Esophageal Sphincter (LES) Stimulation System, a minimally invasive approach to treat severe reflux, reduce symptoms, and improve quality of life. ■

To learn more, go to www.LESSGERD.com

The most important valve for keeping stomach contents out of the esophagus and airway is the lower esophageal sphincter, referred to as the LES.



Normal LES valve keeps food and acid in stomach

Weak LES valve allows food and acid to wash back into esophagus

Still can't find what you are looking for? With almost 5000 pages on our web site, we probably have it covered. Use the search bar located on the top of every page at www.columbiasurgery.org or email us at info@columbiasurgery.org