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Dear Colleague,

For many years, open heart surgery has been the gold standard for replacing narrowed or leaky heart valves and treating atrial fibrillation refractory to medical therapy. Now, advances in catheter-based medical technology have produced an array of new treatment options for patients with these disorders.

This issue of Heart and Vascular Update explores several new technologies being used by the physicians of The Christ Hospital Heart and Vascular Center to both improve patient outcomes while also potentially reducing costs associated with recovering from open heart procedures.

Dolores Enneking is one of the first patients in the Cincinnati region to participate in a clinical trial of the Sapien XT transcatheter aortic valve. Her story (page 4) demonstrates the potential life-transforming value of valve replacement without open-heart surgery.

Meanwhile, The Christ Hospital team has also been evaluating three other devices that have been designed to help patients with atrial fibrillation (AF): the Watchman Left Atrial Appendage Closure Device (currently in clinical trials) and the recently approved Lariat Suture Delivery Device as well as the new Arctic Front Cardiac CryoAblation Catheter System.

These innovative devices offer potential alternatives to traditional surgical and/or medical therapies for patients with atrial fibrillation. We sincerely hope that this information and these new technologies may help you to provide better care for your patients. For more information regarding these exciting new therapies, please contact the Carl and Edyth Lindner Center for Research and Education at 513-585-1777 or visit our website at www.LindnerResearch.com.

Sincerely,

Dean J. Kereiakes, M.D.
Medical Director, Heart and Vascular Center

From the Medical Director

Reducing Stroke Risk
New devices evaluated for preventing clots from common rhythm disorder

Physicians at The Christ Hospital have begun evaluating two devices that have shown early promise at preventing strokes in patients with atrial fibrillation (AF).

Atrial fibrillation, which affects nearly 2.2 million people nationwide, makes the heart less effective at pumping blood. This impaired pumping action can cause blood to pool and form clots in a thumb-sized portion of the heart called the left atrial appendage (LAA). Such clots significantly increase the risk of stroke among AF patients.

Many patients with AF take blood-thinning medications, such as Coumadin or warfarin, to reduce blood clot formation and stroke risk. However, these medications require frequent monitoring and in some cases can lead to serious bleeding complications in the brain or elsewhere in the body. In rare cases, when patients cannot take blood thinners or when medications have failed, surgeons perform open-heart operations to remove the LAA.

Now, several devices that do not require open-heart procedures are emerging to offer an alternative to medication therapy.

Watchman device
Patients at The Carl and Edyth Lindner Center for Research Education at The Christ Hospital are participating in a clinical trial of the Watchman Left Atrial Appendage Closure device, made by Minneapolis-based Atritech Inc. The study is part of an effort to provide additional information for the U.S. Food and Drug Administration (FDA) after an initial study in 2008 provided information regarding the safety and efficacy of the device.

The Watchman device is delivered via a catheter inserted through the groin into the heart and into the narrow left atrial appendage, where it is expanded like an umbrella to seal off blood flow. In eight to 10 weeks, the device completely seals off the LAA from the circulating blood flow in the heart.

“Our hope is that with this device we will be more effective in reducing stroke risk and may replace blood-thinning medications in some patients,” says Madhukar Gupta, M.D., an electrophysiologist with The Christ Hospital, who performed the first procedure in Cincinnati.
The initial study, the PROTECT AF Trial, reported that the Watchman device demonstrated a relative risk reduction in cardiovascular death and stroke versus long-term Warfarin therapy. However, the study also suggested an increased occurrence of safety events when compared to medication therapy. An FDA advisory panel voted seven to five to recommend approving the device with certain conditions, including that procedures be performed in hospitals with open-heart surgical backup, the creation of a physician certification program and extended follow-up of clinical trial participants.

If approved, the Watchman device could become an important treatment option for patients with non-valve-related atrial fibrillation.

**Lariat device**

To participate in the Watchman clinical trial, patients must still be able to take blood thinning medications. However, those who cannot take such medications may benefit from another device now being used at The Christ Hospital – the Lariat Suture Delivery Device, made by SentreHEART of Palo Alto, Calif.

This device is delivered through the chest wall via minimally-invasive techniques, allowing a suture to be looped around the LAA and tied shut, thus sealing off the appendage and preventing blood clots from escaping. The Lariat was cleared by the FDA for use in 2009.

“So far the closure rate for the Lariat device has been excellent, but it remains a very novel technology. It is technically challenging for the physician and may not be the right tool for all patients,” says Joseph Choo, M.D., F.A.C.C., an interventional cardiologist at The Christ Hospital.

“For example, it can be difficult to successfully employ the Lariat device in morbidly obese patients due to difficulty accessing the surface of the heart,” Dr. Choo says. However, the Lariat may be a better option than the Watchman device when the shape of the LAA – which can vary from patient to patient – prevents the Watchman device from producing a satisfactory seal.

“Ultimately, I think we will use both devices,” Choo states.

In years to come, Dr. Choo predicts even more devices will be developed to compete with the Watchman and Lariat devices.

Until recently, medication therapy had been the dominant way of treating AF patients largely because it was difficult to justify the risks and costs of performing open-heart surgery to tie off the LAA. Now, as less invasive technology emerges, these new devices may become the preferred treatment for hundreds of AF patients a year in our region.

For inclusion criteria on this trial and other trial information, please visit cardiovascularresearch.net.

For more information about the Watchman clinical trial, contact The Carl and Edyth Lindner Center for Research and Education at The Christ Hospital at 513-585-1777. For more information about The Christ Hospital Cardiac Rhythm Program, go to www.TheChristHospital.com/rhythm.
Promising Signs
Valve Replacement Without Open Heart Surgery

For two long years, Dolores Enneking watched her life dwindle as her health faded.

Struggling with aortic valve stenosis (AVS), Mrs. Enneking had given up walking two short blocks to her church in Oldenburg, Indiana. She stopped shopping at the local mall. Just getting to the kitchen left her short of breath.

About one in every eight people aged 75 or older has at least moderate AVS, according to the National Heart, Lung, and Blood Institute. For those who can endure the procedure, standard treatment has been open-heart valve replacement surgery.

Mrs. Enneking, now 84, was not a candidate. Several underlying health conditions including a “porcelain aorta” meant that an open heart surgical approach presented an unacceptably high risk of stroke.

Nevertheless, Mrs. Enneking did receive treatment. In June 2011, she traveled to The Christ Hospital Heart and Vascular Center to become one of the first patients from the Cincinnati region to receive the SAPIEN XT transcatheter aortic valve, made by Edwards Lifesciences. The procedure was part of the multi-center PARTNER II trial.

“Now, I have a lot more energy. Before the surgery, I could barely talk on the phone. Now I’m taking two to three little walks a day,” Mrs. Enneking says. “Soon, I will be walking to church again.”

Transformational technology

“This is more than an iterative improvement. This is a game-changer,” says Dean Kereiakes, M.D., medical director of the Heart and Vascular Center. “The opportunity to avoid open-heart surgery is huge. In the short term, this opens doors for older patients who previously were not candidates for valve replacement. But this is just the beginning.”

“For open-heart procedures, patients commonly spend four to seven days in the hospital and several weeks recovering at home before beginning cardiac rehabilitation. However, transcatheter aortic valve replacement (TAVR) can allow patients with mild to moderate risks to be discharged as soon as the next day, almost immediately ready to work on rehab,” Dr. Kereiakes says.

Approved in Europe

While not commercially available in the U.S., the SAPIEN XT valve has been approved in the European Union. However, the first general SAPIEN valve is available commercially in Canada. So far, more than 20,000 people outside the U.S. have received transcatheter valves, including both of the Edwards SAPIEN devices and the CoreValve system made by Medtronic, Inc.

“This is one of the few cardiac procedures where patients are leaving the U.S. to get access to the technology,” Dr. Kereiakes says.

In the U.S., positive results from the initial PARTNER trial were presented in April 2011 at the American College of Cardiology annual meeting in New Orleans. The PARTNER II trial is evaluating a lower profile version of the device.

Continued on top of next page.

Bill Whitt and Delores Enneking, patients who received the Sapien XT device.

For inclusion criteria on this trial and other trial information, please visit cardiovascularresearch.net.
Easier to use

“The smaller SAPIEN XT delivery system is clearly easier to use,” Dr. Kereiakes says.

The first-generation valve required a 24F or 26F vascular access sheath and a minimum iliac vessel diameter of 7 mm or 8 mm for 23 mm and 26 mm valves, respectively. However, the lower profile SAPIEN XT can be delivered through an 18F sheath that requires only a 6 mm iliac vessel, making the TAVR procedure available to a wider range of patients.

Integrated team required

On a cautionary note, the long-term durability of these emerging transcatheter valves remains unknown.

“The longest follow-up so far of the original Sapien device has been about five years.” Dr. Kereiakes says.

Meanwhile, once these new devices win U.S. Food and Drug Administration approval, other factors may limit their general availability. Currently, transcatheter valves can cost as much as $30,000. Americans traveling to Europe pay about $50,000 for the entire procedure. Another limiting factor could be the sheer size of the medical team required to conduct TAVR procedures.

“This is far more complicated than placing a stent. We have 14 to 17 people in the room for this procedure,” Dr. Kereiakes says. “That includes a cardiovascular surgeon, an interventional cardiologist, cardiac anesthesia, cath lab nurses, surgical assistants, imaging specialists and more. Not all hospitals will have the integrated resources to do this.”

Cryo Technology Available for Atrial Fibrillation

Physicians at The Christ Hospital Heart and Vascular Center are now offering a newly approved form of therapy to help patients who suffer from recurrent atrial fibrillation.

The Arctic Front Cardiac CryoAblation Catheter system, made by Medtronic, Inc., received U.S. FDA approval in December for use in treating recurrent symptomatic drug refractory paroxysmal atrial fibrillation, a form of intermittent atrial fibrillation. If left untreated, patients have up to a five times higher risk of stroke and an increased chance of developing heart failure.

The Arctic Front device employs a cryoballoon – rather than radiofrequency (RF) current – to create scar-like lesions around the pulmonary veins during a minimally invasive procedure. Such lesions block the source of erratic electrical signals that cause irregular heartbeats.

“The promise of cryoablation is that the ablation lesions will fully penetrate the wall of tissue around the pulmonary veins and will be distributed in a wider band. This may translate into a more lasting cure of atrial fibrillation,” says Daniel Beyerbach, M.D., Ph.D., medical director, Cardiac Rhythm Program, The Christ Hospital Heart and Vascular Center. “There is increasing evidence that RF ablation may be limited by late recurrence of atrial fibrillation after five years.”

“A disadvantage of cryoablation includes the potential risk of phrenic nerve injury and subsequent paralysis of the hemi-diaphragm,” Dr. Beyerbach adds. “The procedure generally takes longer than RF ablation and manipulation of the catheter to obtain complete pulmonary vein isolation can be technically challenging.”

Cryoablation is more expensive than RF ablation and is approved for use only in a limited group of patients. The device is not indicated for treatment of primary, persistent or chronic atrial fibrillation. The Medtronic device has been used to treat more than 10,000 patients in other nations. U.S. FDA approval was based in large part upon data from the STOP-AF clinical trial, which was presented in March at the American College of Cardiology 2010 Scientific Sessions.

Nearly 70 percent of the 245 patients treated in the study were free of AF symptoms after one year compared to 7.3 percent of patients treated with drug therapy alone. Additionally, patients treated with the Medtronic device displayed a decrease in the use of drug therapy and substantial improvements in both physical and mental quality of life factors.

For more information about cryoablation for treating AF, call 513-585-1328.
Heart Pumps Extending Lives

Once only temporary, improved ventricular assist devices emerge as full treatment option

Of the 670,000 people nationwide who will be diagnosed this year with heart failure (HF), about 134,000 will likely die within a year.\(^1\)

While nearly all heart failure patients receive medications to relieve symptoms and extend their own hearts’ dwindling pumping capacity, only about 2,200 people\(^2\) each year will get a more hopeful, more restorative treatment - a heart transplant.

A chronically low supply of donor organs has prevented heart transplantation from becoming a common treatment, even for those who have reached end-stage HF. However, evolving technology offers a new option that likely will become more common in the near future.

A small but growing number of HF patients are gaining years of significantly improved life after receiving left ventricular assist devices (LVADs) as either a bridge to full organ transplantation or for permanent implant, also called destination therapy.

“This is the future of end-stage heart failure treatment,” says Santosh Menon, M.D., medical director of the Mechanical Heart Assist Device Program at The Christ Hospital Heart and Vascular Center. “As these devices continue to get better and more affordable, there will be few if any limitations to their use.”

The growing availability of LVADs is especially important in Greater Cincinnati, because no adult hospital in the city offers heart transplantation. Currently, at least 200 local heart failure patients could be serious candidates for LVADs,” Dr. Menon estimates.

“A very large population may eventually benefit from LVADs,” says Tom Ivey, M.D., a cardiothoracic surgeon involved in the Mechanical Heart Assist Device Program.

“More people are living longer, yet the donor pool is getting smaller,” Dr. Ivey says. “Once people get into their 70s and beyond, many patients with heart failure also develop other conditions that rule them out for heart transplants. For the large majority of these patients, medications have been the only option.”

So far, seven patients have received these life-altering devices through the new Mechanical Heart Assist Device Program, launched in Fall 2010. All five patients received the devices as bridge-to-transplant therapy.

The program expects to receive approval later this year to implant LVADs as destination therapy, which will make the device available to more patients who may not qualify for heart transplants.

Greg Egnaczyk, M.D., Ph.D., explains, “Many patients with advanced heart failure are not eligible for heart transplantation, including people over the age of 70. Destination LVAD therapy provides the hope of longer and fuller lives to these patients.” Dr. Egnaczyk was recently recruited to join the advanced heart failure and mechanical heart assist device program at The Christ Hospital from Duke University, where he received specialized training in advanced heart failure treatment and mechanical devices.

Small but powerful

All the patients received the HeartMate II, a device made by California-based Thoratec Corp.

The HeartMate II device requires surgery to attach a small mechanical pump to the failing heart. The improved device has just a single moving part, yet is powerful enough to fully replace the pumping function of the left ventricle. The internal pump is connected by cable to an external system controller (worn on the belt) and a battery pack (typically worn as a harness).

The device allows people to return to most daily activities, with batteries lasting about 10 hours between charges.

“Our patients report feeling dramatically better, as if five years of constantly feeling like they had the flu has suddenly ended. We have had patients return to work, play golf, even take small trips,” Dr. Menon says.
Cardiac surgeon Robert Gallegos, M.D., Ph.D., a new member of the Heart and Vascular Center team, says the biggest limitation to current LVADs are the small cords or wires exiting the body, which require constant attention to hygiene to prevent infection.

“In the near future, these types of devices will become completely implantable, which will allow patients to lead even more active lives,” Gallegos says.

Currently, the device costs about $60,000; the entire procedure costs about $100,000. Medicare, Medicaid and most private insurers cover this treatment.

The costs involved are similar in scale to performing a heart transplant. However, patients receiving LVADs do not require a lifetime of immune suppressing anti-rejection medications.

“Early on, I was concerned that these devices would be cost-prohibitive,” Dr. Ivey says. “However, once the device is implanted, most patients stay out of the hospital over time.”

Education required

Our physicians constantly remind patients that LVADs represent new technology. These devices require understanding and commitment from the patient to properly operate and maintain.

Patients in The Christ Hospital program do not leave the hospital until completing a comprehensive education process - including home inspections and supervised trial runs to ensure that patients can manage the device. In fact, LVADs remain uncommon enough that when patients go home, hospital staff meets with local fire departments to train emergency medical service teams how to change out controllers and battery packs if necessary on emergency calls.

Longer, better lives

For those who receive heart transplants, about 88 percent survive the first year, 50 percent survive 10 years and 16 percent survive 20 years.3 It remains too early to tell how long LVAD devices will last.

About 68 percent of patients survived one year and 58 percent survived two years after receiving the HeartMate II device, according to a study presented in November 2009 at the American Heart Association’s Scientific Sessions in Orlando, FL.4

That two-year survival rate represents a dramatic improvement over the eight percent two-year survival rate for end-stage HF patients receiving medical therapy alone, as reported in the multi-center REMATCH clinical trial.5

1. Centers for Disease Control and Prevention (CDC)
Heart Failure Fact Sheet
http://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_heart_failure.htm

2. Organ Procurement and Transplantation Network (OPTN)
US Transplants Performed, Jan 1988-Apr 2011
http://optn.transplant.hrsa.gov/latestData/rptData.asp
Current US waiting list, by organ
http://optn.transplant.hrsa.gov/latestData/rptData.asp

3. National Heart Lung and Blood Institute (NHLBI)
What is a heart transplant?

4. New England Journal of Medicine
Advanced Heart Failure Treated with Continuous-Flow Left Ventricular Assist Device

5. New England Journal of Medicine
Long-Term Use of a Left Ventricular Assist Device for End-Stage Heart Failure
Surgeon-scientist Joins the Team

The Christ Hospital Heart and Vascular Center welcomes Robert Gallegos, M.D., Ph.D., to our team.

Dr. Gallegos comes to Cincinnati from Boston, where he was a member of the Department of Surgery at Brigham and Women’s Hospital, an affiliate of Harvard University. In addition to being an accomplished surgeon, Gallegos brings considerable research experience, particularly in using stem cell therapies to regenerate cardiac tissue.

Dr. Gallegos, 40, is trained as a cardiac surgeon and in bioengineering. He earned a bachelor’s degree in bioengineering and his medical degree from the University of California, San Diego. He completed his Ph.D. in Experimental Surgery at the University of Minnesota, where he also served his residency and a fellowship in surgical infectious disease. He went on to complete a fellowship in cardiac surgery at Brigham and Women’s Hospital, where he led an active surgical practice, conducted research and provided training to other physicians.

Much of his research focused on using stem cell therapy to induce myocardial regeneration. He helped develop animal models to study stem cell therapy approaches and has been involved in examining bioengineered peptides that are designed to serve as scaffolds for cell engraftment and growth.

“I was attracted to the very positive mix of private practice and research occurring here. It is hard to find this level of research in a private practice environment,” Dr. Gallegos says.

Dr. Gallegos plans to settle in Indian Hill, where he will live with his wife and three children.

MRI Appointments Available on Sundays at The Christ Hospital Imaging Center on Red Bank

The Christ Hospital (TCH) Imaging Center on Red Bank Expressway in Madisonville will be open Sundays, noon to 6 p.m., for MRI studies. Appointments can be scheduled by calling 513-585-2668. In addition to high-field Open MRI, TCH Imaging Center offers digital mammography (screening and diagnostic), DEXA, CT, ultrasound – general and vascular – and digital X-ray, Monday through Friday, 7 a.m. – 8 p.m. and on Saturday, 7:30 a.m. – 4 p.m. For more information, please visit www.TheChristHospital.com/ImagingCenter.