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

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**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.