Percutaneous Repair of Mitral Valve Regurgitation Gets Two Steps Closer to Reality

Repair of mitral valve regurgitation currently requires open-heart surgery with cardiopulmonary bypass. Unfortunately, many patients with such valve leakage have congestive heart failure and are often not healthy enough to withstand the rigors of this traditional approach. However, this restriction may soon be overcome if two procedures now undergoing early clinical testing at The Cleveland Clinic can effectively demonstrate that such valve repairs can also be done percutaneously. Even modest mitral regurgitation can lead to progressive ventricular dilatation and a growing distortion of normal valve geometry — opposing leaflets begin to slip out of alignment and supporting structures, such as the valve annulus, may dilate, further compromising heart hemodynamics.

Traditional repair of such regurgitation typically involves two major steps. First, repairing the valve apparatus itself, which sometimes involves partially sewing the mitral valve leaflets together along their medial edges, a technique known as the edge-to-edge or Alfieri procedure. (Note: this procedure is not always used.) This leaves openings both above and below the partially co-joined leaflets to act as a reduced double orifice. And, second, placing a ring structure (such as the Cosgrove ring) around the dilated annulus in order to reshape it and restore more normal valve geometry.

It is these two steps that Clinic researchers are attempting to mimic using new techniques and technology delivered at the end of a catheter.

In the first phase I trial — EVEREST (Endovascular Valve Edge-to-Edge Repair Study) — cardiologists are investigating whether a small metal clip, delivered and positioned by catheter, can safely hold the mitral valve leaflets together. Patients who consent to this trial have moderate to severe mitral regurgitation, symptoms of fatigue, chest pain and shortness of breath; or if lacking these, a weakened left ventricle.

Referral Information: To refer patients to Cleveland Clinic cardiologists or cardiothoracic surgeons for specialized imaging, bypass surgery, valve repair, complex arrhythmia management, congenital heart defect repair, angioplasty, or general cardiac problems, please call 216/444-6697 or 800/553-5056.

Cardiac Consult provides information from Cleveland Clinic Heart Center specialists about state-of-the-art diagnostic and management techniques. Please direct correspondence to:

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Web Site: The Cleveland Clinic Heart Center’s World Wide Web site — clevelandclinic.org/heartcenter — offers information on new procedures and services, clinical trials, and upcoming CME symposia, as well as recent issues of Cardiac Consult magazine.

The Cleveland Clinic Heart Center, recognized as an international cardiovascular referral center, accommodates more than 200,000 patient visits each year in world-class facilities. Heart Center staff are committed to researching and applying state-of-the-art diagnostic and management techniques. The Heart Center is part of The Cleveland Clinic, an independent, not-for-profit, multi-specialty academic medical center.

Cardiac Consult is written for physicians and should be relied upon for medical education purposes only. It does not provide a complete overview of the topics covered, and should not replace the independent judgment of a physician about the appropriateness or risks of a procedure for a given patient.

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The catheter (shown in white) resides within the coronary sinus, which is in close proximity to the posterior valve annulus.

The prosthesis (shown within catheter) straightens the natural curvature of the vein and exerts pressure on the dilated annulus, pushing it and its attached leaflet forward to help restore more normal valve leaflet alignment.

Prosthesis helps restore normal valve alignment and hemodynamics.

“We use ultrasound and fluoroscopy to guide placement of the clip, which connects the leaflet edges,” says Stephen Ellis, M.D., Director, Sones Cardiac Laboratories and Co-Director, Cardiac Gene Bank, Cleveland Clinic Heart Center.

Placement of the single metal clip is adjusted until optimal improvement in hemodynamics is observed; then the clip is given final release and the catheter withdrawn. Patients are put on blood thinners for the six weeks it takes sufficient scar tissue to form over the clip.

The Clinic’s co-principal investigators
Dear Colleagues:

As the new medical editors of the Cleveland Clinic Heart Center’s flagship publication, we’d like to welcome you to another issue of Cardiac Consult. For more than a decade, Cardiac Consult has chronicled Heart Center efforts in research and clinical care. More often than not, the stories presented here demonstrate the Heart Center’s leadership role in finding novel solutions to an array of cardiac problems, as well as spearheading or collaborating on clinical trials that advance the management of heart disease. These efforts arise from collective perseverance, collaboration, innovation and creativity, attributes that abound in medicine but that are not always easily harnessed.

Cardiology has a common nemesis in plaque, but as you well know, in the past several years the field has moved ever closer to taming that foe surgically and medically. As our colleague Eric J. Topol, M.D., noted in a recent New England Journal of Medicine editorial, the remarkable findings demonstrating the power of intensive statin therapy mark a sea change in cardiovascular prevention. Indeed, research performed by Heart Center physicians has played a key role in spurring this sea change. In this and subsequent issues, you will read about these and other efforts that are helping reshape and redefine management of heart disease.

Highlighting this issue is a story about a special form of HDL, ApoA-I Milano, recently shown to reverse atherosclerosis. The drug’s remarkable potential was demonstrated using intravascular ultrasound, a technology the Heart Center has been cultivating for more than a decade. Our second feature reports on two percutaneous approaches for mitral valve repair that may one day offer an alternative to invasive surgery. An update from the Clinic’s Kaufman Center for Heart Failure outlines some of their key goals and objectives. Finally, a story reporting a new partnership between the Heart Center and a medical center in the Northeast highlights the Clinic’s first collaboration with another cardiothoracic surgery program outside of Ohio. We hope you find these stories engaging and informative, and we invite your comments on the issues explored here.

Sincerely,

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for this trial are Patrick Whitlow, M.D., and Murat Tuzcu, M.D. Other centers taking part in this study sponsored by Evalve, Inc. (Redwood City, CA), are: Evanston Northwestern Healthcare (Illinois); the University of Pennsylvania; Emory University (Atlanta); the Swedish Medical Center (Seattle), and Washington Hospital Center (Washington, D.C.).

Though this trial is still underway — eight patients have received the clip so far — researchers are tentatively planning the next phase for sometime in 2005.

In the other phase I trial, Clinic cardiologists and cardiothoracic surgeons are testing a prosthesis that is deployed in the coronary sinus via a catheter. Placement of the device pushes the support structures of the mitral valve and its leaflets back into more normal alignment, mimicking a surgical annuloplasty (see images). Patients in the study have already consented to have mitral valve surgery.

According to Dr. Ellis, the prosthesis is a metal bar, about 7 cm in usable length and 1.5 mm in diameter, flexible at both ends and stiff in the middle. Guided by fluoroscopy and transesophageal echocardiography, the bar is positioned within the coronary sinus, near the posterior valve annulus. By exerting pressure on the dilated annulus and pushing it and its attached leaflet closer toward its twin, the device helps restore more normal valve alignment and hemodynamics.

This study, too, is in its early stages. To date, five patients at CCF have been enrolled. The two other centers involved in this preliminary study — funded by Viacor, Inc. (Wilmington, MA) — are in Germany and in Montreal. The next phase of this research is likely to begin in 2005.

Although these percutaneous approaches for repairing leaky valves have not yet been validated in large clinical trials, they are an important step on the way to a less invasive treatment for mitral regurgitation.
**Clinic Heart Center, Rochester, Forge New Partnership**

**Rochester General Hospital** and The Cleveland Clinic have established a formal cardiothoracic surgery partnership that will significantly strengthen the cardiac care program offered by the Rochester, NY medical center. Building on the tradition of excellence in cardiac care at each medical center, the partnership will generate opportunities to provide new treatments and therapies to Rochester General patients and accelerate mutual accomplishments in leading-edge cardiac care. This is the first major collaboration The Cleveland Clinic has initiated with another cardiothoracic surgery program outside of Ohio. The collaboration was formalized in late 2003.

Under the partnership, many Cleveland Clinic Foundation and Rochester Heart Institute clinical policies, treatment protocols and research opportunities will be shared. To enhance clinical integration, Rochester General’s cardiovascular surgeons — Ronald L. Kirshner, M.D., David C. Cheeran, M.D., and G. Randall Green, M.D. — will be members of The Cleveland Clinic staff and will participate in its clinical conferences and educational programs.

“Rochester General has an excellent cardiac surgical program,” says Delos M. “Toby” Cosgrove, M.D., CCF department chairman of thoracic and cardiovascular surgery. “That’s why we chose them as our first ever out-of-state partner. Our combined efforts will enhance the outstanding programs both institutions have established. We believe this collaboration is a win for all involved, especially the patients.”

“We have always provided top-quality cardiac care to the residents of Western New York,” said Dr. Ronald Kirshner, Rochester General’s chief of cardiac services and cardiothoracic surgery. “By seeking out this partnership with the international leaders in cardiac care, we continue to provide world-class care close to home.” Dr. Kirshner noted that The Cleveland Clinic “invented coronary angiography, performed the first cardiac bypass and continues to lead the way in developing state-of-the-art cardiac treatments. The opportunity to partner with the nation’s leader in heart care is a tremendous opportunity for Rochester.”

**George M. and Linda H. KAUFMAN CENTER for HEART FAILURE**

**Broadened Horizons, New Challenges for Kaufman Center Director**

**AS A RECREATIONAL** mountain climber, James B. Young, M.D., knows that even when there are multiple routes leading to a summit, you can only take one path at a time. So maybe that’s why he’s a physician first, a climber second. Because in medicine, there are many paths to a summit, and often they can be taken simultaneously.

For more than a decade-and-a-half, Dr. Young has been collaborating with colleagues to cut many a path toward a better understanding of heart failure. As medical director of the Clinic’s Kaufman Center for Heart Failure, Dr. Young has staged or collaborated on dozens of clinical efforts to improve treatment of a disease estimated to affect 5 million Americans.

In his new roles as chairman of the division of medicine, Cleveland Clinic, and academic chairman of the department of medicine of the new Cleveland Clinic Lerner College of Medicine, Dr. Young hopes to cultivate collaborations that will produce significant and lasting advances for the management and treatment of an array of diseases and conditions.

**Parlaying Key Strengths**

Dr. Young came to The Cleveland Clinic in 1995 as head of the section of heart failure and cardiac transplant medicine. Shortly thereafter, in 1998, he joined forces with colleague Patrick M. McCarthy, M.D., to oversee a clinical and research effort that would occur under the auspices of the newly established Kaufman Center. Dr. McCarthy became surgical director of the center; Dr. Young its medical director.

During the last decade, Dr. Young served as principal or co-investigator in the U.S. of numerous multi-center clinical trials, including RESOLVED and MIRACLE-ICD. In 2002, Dr. Young became vice chairman of the department of cardiovascular medicine. Just a year later, in November 2003, he was appointed chairman of the division of medicine, and academic chairman, department of medicine, Lerner College.

In fact, the Baylor College of Medicine graduate wants to use the experience of the Kaufman Center to help guide the direction of the division of medicine, which comprises more than a dozen departments and centers, including cardiovascular medicine; emergency medicine; endocrinology, diabetes and metabolism; gastroenterology; infectious disease; and pulmonary, allergy and critical care medicine.

One of the Clinic’s key inherent strengths, says Dr. Young, is the interdisciplinary approach it uses to treat disease and solve medical-science puzzles. There also is strength in numbers, and the Clinic has specialists representing well more than the average array of medical conditions treated by other, smaller medical centers.

“What I hope to do,” says Dr. Young, “is create a broader interchange between the different disciplines, such that there will be a much stronger grouping of people who can act as a unit, to both provide outstanding patient care, but also to achieve the academic mission of the Clinic. This includes the education of our patients, medical students, residents and fellows, as well as the public. It also includes continued research into a spectrum of disease processes.”

As an example of one important proposed collaboration, Dr. Young hopes to mobilize experts from cardiology, preventive cardiology and endocrinology to develop strategies to help minimize the risk of people developing metabolic syndrome and diabetes, or if they do develop these conditions, create more effective treatments to gain tight control over them. Such an effort, says Dr. Young, could help decrease the ranks of those diagnosed — upward of 500,000 — with heart failure every year. “We have the ability to have an impact in this area,” he says.

Another example, says Dr. Young, would be nurturing existing joint efforts by experts in neurology, neurosurgery and psychiatry to offer patients better and more effective treatments for conditions such as bipolar...
focus for the near future: says the Kaufman Center has three areas of focus, the Lerner Research Institute, and surgical labs (where heart failure research occurs), the Lerner Research Institute, and many other departments and centers. He says the Kaufman Center has three areas of focus for the near future:

- Clarification of the pathophysiology of heart failure (e.g., the molecular changes that drive and occur because of heart failure; genetic aspects of heart failure)
- Broadening clinical treatment approaches (e.g., medication therapies, immunomodulation strategies, pacemaker strategies)
- Continued development of novel surgical interventions — (e.g., managing/ reversing heart remodeling, reshaping heart structure, repairing leaky valves)

Many Important Advances

Since opening in 1998, Kaufman Center efforts have resulted in a number of important advances in the management and treatment of heart failure. These include more selective use of diuretics and investigation of new agents, such as nesiritide (a recombinant form of human B-type natriuretic peptide), and developing new approaches and techniques for mitral valve repair and left ventricular reconstruction. For patients in end-stage systolic heart failure, the center took the lead in demonstrating the effectiveness of implantation of left ventricular assist devices. And in 2003, the Kaufman Center performed its 1,000th heart transplant. Other Kaufman Center accomplishments include:

- Demonstrating the effectiveness of transvenous biventricular cardiac resynchronization for improving cardiac output and energetics.
- For patients at high risk of sudden death, implantation of a combination defibrillator/biventricular pacemaker to achieve atrial-synchronized biventricular pacing, and, in turn, improved quality of life and NYHA status (Multicenter InSync Randomized Clinical Evaluation, or, MIRACLE trial).
- Investigation of innovative surgical devices to help stop and even reverse remodeling. For instance, the Acorn cardiac support device is a bio-compatible, mesh-like jacket that enwraps the ventricles and reduces stress-mediated myocardial stretch. More than 50 Acorn devices have been implanted through the Kaufman Center.
- For patients undergoing heart transplant, the Kaufman Center provided the first successful implantation of a bio-compatible, mesh-like jacket that enwraps the ventricles and reduces stress-mediated myocardial stretch.

Kaufman Center Goals

Despite his new responsibilities, Dr. Young will continue in his role of directing Kaufman Center medical initiatives and activities. However he’s now joined in that effort by Randy Starling, M.D., M.P.H., co-medical director of the center. Dr. Starling also is section head of heart failure and cardiac transplantation at the Clinic.

“The Clinic,” says Dr. Young, “has one of the largest heart failure research efforts in the country. When you couple our efforts in clinical and translational research, we really play a prominent role in this field.”

Dr. Young characterizes the Kaufman Center as “a model of interdisciplinary interaction” that works closely with surgery, surgical labs (where heart failure research occurs), the Lerner Research Institute, and many other departments and centers. He says the Kaufman Center has three areas of focus for the near future:
Like many cardiologists, Stephen Nissen, M.D., and his colleagues spend a good part of their lives ruminating about plaque, and more specifically, dreaming up ways to get it out — and keep it out — of arteries. In some ways, thanks to a keen interest in intravascular ultrasound, Dr. Nissen has a unique relationship with atherosclerosis, because he sees it up close and often.

Atherosclerosis is a silent, constant nefarious work in progress whose lifeblood is cholesterol. It also is a condition with volcanic-like tendencies in the form of unstable plaque, and these tendencies can kill. Plenty of inventive surgical interventions have been dreamed up over the years to help manage atherosclerosis, and several drugs are now used to help keep plaque progression at bay. But plaque develops over decades, and removing it with a combination of drugs, diet and exercise can be an equally time-intensive pursuit, with results varying widely. Not a great proposition for patients with acute heart conditions. Direct interventions — coronary artery bypass surgery and percutaneous coronary intervention — are costly, can be complex, are often contraindicated and can only treat a small portion of what is often a systemic problem.

So what would really help, what could really be a significant complement to existing strategies, is a drug that literally clears plaque, and does so safely and quickly. As much of the world learned in November 2003, such a drug may already exist.

Dr. Nissen and colleagues from the Cleveland Clinic have been working for years on a synthetic version of an apolipoprotein-A variant discovered in the late 1970s among several dozen inhabitants of a tiny Italian coastal village (see sidebar). Apolipo-protein A is a major protein of high density lipoprotein cholesterol. The researchers showed that ApoA-I Milano could significantly reverse atherosclerosis and do so in a matter of weeks. The findings were published in the November 5, 2003 JAMA.

“...the hope of lowering LDL and raising HDL cholesterol levels to decrease the risk of heart attack and stroke. But the effects of these approaches vary widely among individuals, require lots of discipline by patients, and more important, require lots of time, something many patients with acute heart disease have in short supply. Moreover, no drug can significantly elevate HDL levels and no definitive data shows that doing so would reduce the risk of heart attacks and stroke."

So the idea behind using ApoA-I Milano is to bolster reverse cholesterol transport, the system responsible for removing excess cholesterol and other lipids from artery walls and other tissues and transporting them to the liver for elimination.

“We think the drug turns on reverse cholesterol transport more efficiently than ordinary HDL would,” says Dr. Nissen, Medical Director, Cardiovascular Coordinating Center, Cleveland Clinic Heart Center.

The ApoA-I Milano study marks a significant departure from existing tactics for managing and controlling atherosclerosis. Such tactics rely on drugs, diet and exercise, with the hope of lowering LDL and raising HDL cholesterol levels to decrease the risk of heart attack and stroke. But the effects of these approaches vary widely among individuals, require lots of discipline by patients, and more important, require lots of time, something many patients with acute heart disease have in short supply. Moreover, no drug can significantly elevate HDL levels and no definitive data shows that doing so would reduce the risk of heart attacks and stroke.

The double-blind, randomized, placebo-controlled multicenter pilot trial compared the effects of the study drug (ApoA-I Milano-phospholipid complex, or ETC-216) with those of placebo on coronary atheroma burden in 57 patients who had experienced an acute coronary syndrome (ACS), either unstable angina or heart attack. Intravascular ultrasound (IVUS) was used to measure coronary atheroma volume prior to and after initiation of study drug or placebo. Study participants ranged in age from 30 to 75, were male and white.

Patients were randomly assigned to infusions — once per week for five weeks — of placebo, low-dose ETC-216 (15 mg/kg), or a high-dose ETC-216 (45 mg/kg). In all, 47 patients finished the protocol — 11 in the placebo, 21 in the low-dose and 15 in the high-dose groups. Intravascular ultrasound was performed within two weeks following an ACS event and repeated after completion of the study protocol. Results from IVUS imaging were used to calculate atheroma volume in a targeted segment of coronary artery. Results showed an absolute reduction in atheroma volume of 4.2% from baseline levels. The trial was conducted in 10 community and tertiary care hospitals throughout the United States.

**Cover Story**

**IVUS Shows Experimental Agent’s Remarkable Attack on Plaque**

**Study Nuts and Bolts**

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**Departure From the Past**

The ApoA-I Milano study marks a significant departure from existing tactics for managing and controlling atherosclerosis. Such tactics rely on drugs, diet and exercise, with the hope of lowering LDL and raising HDL cholesterol levels to decrease the risk of heart attack and stroke. But the effects of these approaches vary widely among individuals, require lots of discipline by patients, and more important, require lots of time, something many patients with acute heart disease have in short supply. Moreover, no drug can significantly elevate HDL levels and no definitive data shows that doing so would reduce the risk of heart attacks and stroke.

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“We think the drug turns on reverse cholesterol transport more efficiently than ordinary HDL would,” says Dr. Nissen, Medical Director, Cardiovascular Coordinating Center, Cleveland Clinic Heart Center.

“Now, everyone knows we didn’t test the effects of normal ApoA-I and one of the questions is whether it could produce the same effect. I don’t believe it would.”

But the answer to the question also may not matter, partly because using normal ApoA-I is not patentable — and therefore
Door Is Open, But Much to Learn

Dr. Nissen emphasized that the ApoA-I Milano clinical trial was a small “proof of concept” study, designed only to demonstrate the potential of the new therapy, and much more research has to be done before the drug can be used clinically. He also emphasized that ApoA-I Milano is still an experimental drug. He says no related clinical trials are underway or planned for the near future, there has been no Food and Drug Administration approval of the drug (including any stipulation for “compassionate use”), no patients are currently being recruited to participate in any trials and no study drug is available for any use whatsoever.

Once it is up and running, Dr. Nissen says the next trial will try to answer two very important questions: “One, whether giving the drug for 10 weeks rather than 5 produces even further atherosclerotic regression, and two, because the first study showed no difference in dose response, what is the minimum effective dose?” Another issue is the drug’s effect on unstable plaque.

“Most of what’s known about vulnerable plaque suggests that a strategy like this ought to help. But we just don’t know. And that’s one of the things we’ll look into.”

Still, he is optimistic about medicine’s ability to use drugs to tame atherosclerosis and about ApoA-I Milano’s role in helping achieve that.

“Half the population dies of atherosclerotic complications. The burden of this disease in Western society is enormous. If we can remove some of the plaque and return the arteries to a more healthy state, similar to what they were when people were younger, we really can turn back the clock on this disease. Now, we’re not there yet — this opens the door to that. But the door popped open in a way that no one expected it to.”

Secret Is Revealed in Remote Coastal Town

Limone sul Garda is a small coastal resort, situated on the western shores of Lake Garda, in the province of Brescia, in Northern Italy. Until the ApoA-I Milano findings were published, it was far better known for its luscious scenery and serene atmosphere than it was for the HDL cholesterol levels of a handful of its 1,000 inhabitants.

Some 25 years ago, one of Limone sul Garda’s male residents visited a medical clinic in Milan. A blood test showed unusually low levels of HDL-C, yet the man had no signs nor symptoms of heart disease. Intrigued by the findings, a handful of Italian researchers investigated. The research produced an article in 1980 that reported on 40 residents of Limone sul Garda, all of whom carried a naturally occurring variant of apolipoprotein A-I, the major protein of high density lipoprotein cholesterol, or HDL-C. The researchers also found that despite abnormally low HDL-C levels, the study subjects generally showed no clinical signs of atherosclerosis. In a tip of the hat to the city in which the laboratory analysis was done, the researchers named the variant protein ApoA-I Milano.

At the time the phase II trial was completed, the recombinant ApoA-I Milano-phospholipid complex drug was owned by Esperion Therapeutics Inc., an Ann Arbor, Michigan-based biopharmaceutical company. In December 2003, Esperion was acquired by Pfizer Inc. for $1.3 billion.
Heart Center Grand Rounds
All physicians are welcome to attend Heart Center Grand Rounds, 7:30 a.m., Fridays, Bunts Auditorium (TT Building). Most visiting professors also stay through the afternoon to participate in our “Controversies in Cardiology” sessions.
May 21
Current Concepts and ’What’s New’ in Valvular Heart Disease
Thomas M. Bashore, M.D.
Professor of Medicine
Director, Fellowship Training Program
Duke University Medical Center
Durham, NC

June 4
Catherine DeAngelis, M.D., M.P.H.
Editor
JAMA (journal of the American Medical Association)

June 11
Remote Controlled Magnetic Guidance
Bruce D. Lindsay, M.D.
Associate Professor of Medicine
Director, Clinical Electrophysiology Laboratory
Washington University School of Medicine
St. Louis, MO

June 18
Pharmacogenetics in Heart Failure: The New ’Tailored’ Therapy
Dennis M. McNamara, M.D.
Director, Heart Failure Section
Associate Professor of Medicine
University of Pittsburgh Medical Center
Pittsburgh, PA

Heart Center CME Symposia
The Cleveland Clinic Heart Center invites physicians from other institutions to attend the following CME-accredited symposia:
June 6-11
16th Annual Intensive Review of Internal Medicine
Course #011323
InterContinental Hotel & MBNA Conference Center, The Cleveland Clinic
Cleveland, OH

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THE CLEVELAND CLINIC FOUNDATION

September 19-24
Cardiology Board Review
Course #011313
InterContinental Hotel & MBNA Conference Center, The Cleveland Clinic
Cleveland, OH

October 1-2
Arrhythmia Workshop
Course #011346
InterContinental Hotel & MBNA Conference Center, The Cleveland Clinic
Cleveland, OH

October 7-10
Heart Failure & Rotary Blood Pump Summit
Course #011318
InterContinental Hotel & MBNA Conference Center, The Cleveland Clinic
Cleveland, OH

November 14-16
24th Annual Dimensions in Cardiac Care
Course #011307
InterContinental Hotel & MBNA Conference Center, The Cleveland Clinic
Cleveland, OH

Heart Center Staff Updates

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