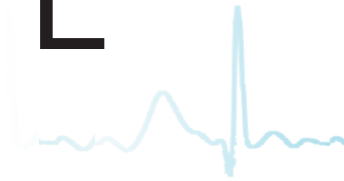


HEARTLINE

V3 / No. 1 / Spring 2014



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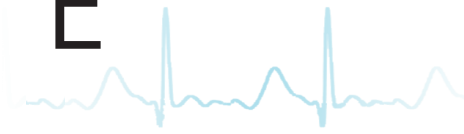
Montefiore
Montefiore Einstein
Center for Heart &
Vascular Care

A Message from Robert E. Michler, MD, and Mario J. Garcia, MD

Cardiologists and cardiothoracic surgeons working together for the good of the patient. It seems like a commonsense approach to care. Yet at hospitals across the nation, the two specialties often operate in silos. Under this model, patients may see a cardiologist one day, undergo diagnostic testing on another, and meet with the cardiothoracic surgeon weeks later.

... continued on page 1

HEARTLINE



To read more about the accomplishments of the Montefiore Einstein Center for Heart & Vascular Care, visit www.montefiore.org/heartline.



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Montefiore Einstein Center for Heart & Vascular Care

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IMAGE CREDITS

Cover and page 2: Valve image courtesy of Edwards Lifesciences Corporation
Page 4: LARIAT® Suture Delivery Device image courtesy of SentreHEART, Inc.

A Message from Robert E. Michler, MD, and Mario J. Garcia, MD

continued from cover

This approach can inconvenience patients and potentially compromise outcomes.

In the past several years, Montefiore made the conscious decision to turn this paradigm on its head and create the Montefiore Einstein Center for Heart and Vascular Care, a unified environment that fosters mutual respect and collaboration between the two specialty areas.

Both patients and physicians have benefited greatly from this shift. For example, patients are now seen by their cardiologist and surgeon simultaneously. At the end of this appointment they have received a diagnosis, a defined treatment plan and, if needed, a date for surgery.

When dealing with complex cases, our physicians draw upon the expertise of their colleagues during the Center's weekly C-4 Conference. This conference brings cardiologists, computed tomography (CT) surgeons, radiologists and other specialists together in a dynamic forum, during which data is examined, treatments are analyzed and customized care plans are developed.

Collaboration between the specialties has also opened the door to new, exciting treatment opportunities. Our Transcatheter Aortic Valve Replacement (TAVR) Program for the treatment of severe aortic stenosis is a prime example. The patients who come to us through this program are very sick and often at risk for surgery. Physicians from Cardiology and Cardiothoracic Surgery meet with these individuals and collaborate to determine whether TAVR will offer them an improved quality of life. When a patient meets the TAVR criteria, we pay a high level of attention to achieving exceptional results, including a procedural success rate of 100 percent. When TAVR isn't an option, we have consistently been able to offer the patient a promising alternative, which wouldn't be possible without teamwork. Another area where collaboration is crucial is in evaluating and treating patients with mitral valve disease. Our cardiologists possess unrivaled diagnostic expertise and work diligently to determine which of these patients would benefit from medical therapy and which require surgery. If surgery is required, the cardiologists' groundwork guides the procedure. This is particularly true with a complex form of mitral valve repair called the butterfly

“At Montefiore, we value the relationships that we have established with our patients, our clinical specialists and our referring physicians.”

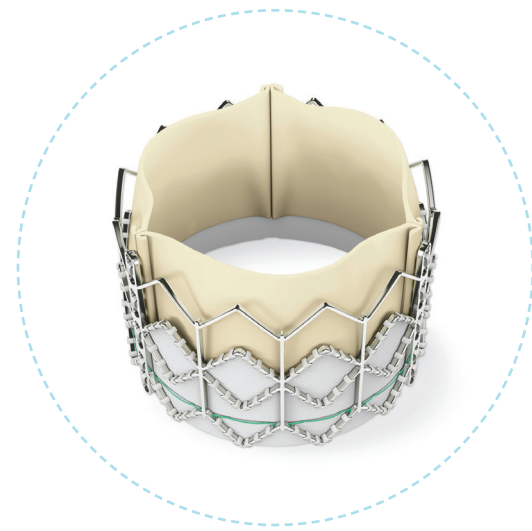
approach. There is no margin for error with this surgery, and the images and data obtained by our cardiologists during the evaluation are crucial in the planning and successful execution of this treatment.

People often say that relationships are everything, and in the area of heart care, this certainly holds true. At Montefiore, we value the relationships that we have established with our patients, our clinical specialists and our referring physicians. We credit our superior outcomes to the seamless collaboration that we enjoy with them. Thank you for entrusting us with your patients and for being our partner in care. If there is anything we can do to enhance our services for you or your patients, please let us know.

Sincerely,

Robert E. Michler, MD
Surgeon-in-Chief
Professor and Chairman
Department of Cardiovascular and Thoracic Surgery and the
Department of Surgery
Samuel I. Belkin Chair
Co-Director, Montefiore Einstein
Center for Heart and Vascular Care

Mario J. Garcia, MD
Professor and Chief
Division of Cardiology
Pauline Levitt Chair in Medicine
Co-Director, Montefiore Einstein
Center for Heart and Vascular Care



Improving the Outlook for Patients with Inoperable or Extreme-Risk Aortic Stenosis

Using a revolutionary procedure, Montefiore cardiac specialists are helping individuals who are desperately ill, but who might not be able to undergo conventional open heart surgery.

Transcatheter aortic valve replacement (TAVR) was introduced at Montefiore in 2012 as a treatment alternative for elderly patients with severe aortic stenosis who were deemed to be too ill for surgery. The members of Montefiore's TAVR team have operated on more than 50 patients. "In all of these cases, the procedural success rate was 100 percent," says David Paul Slovit, MD, PhD, Co-Director, TAVR Program, Montefiore Einstein Center for Heart and Vascular Care, Montefiore, and Associate Professor, Clinical Medicine and Cardiovascular and Thoracic Surgery, Einstein. "The majority of the patients in this fragile population have done very well, with many of them experiencing significant improvements in breathing and exercise tolerance."

Montefiore's first few TAVR cases were performed using a transfemoral approach, during which the bioprosthetic valve was threaded through the femoral artery using a catheter to place it into the heart. Once in position, balloon dilation was performed to deploy the replacement valve and its frame within the diseased native aortic valve.

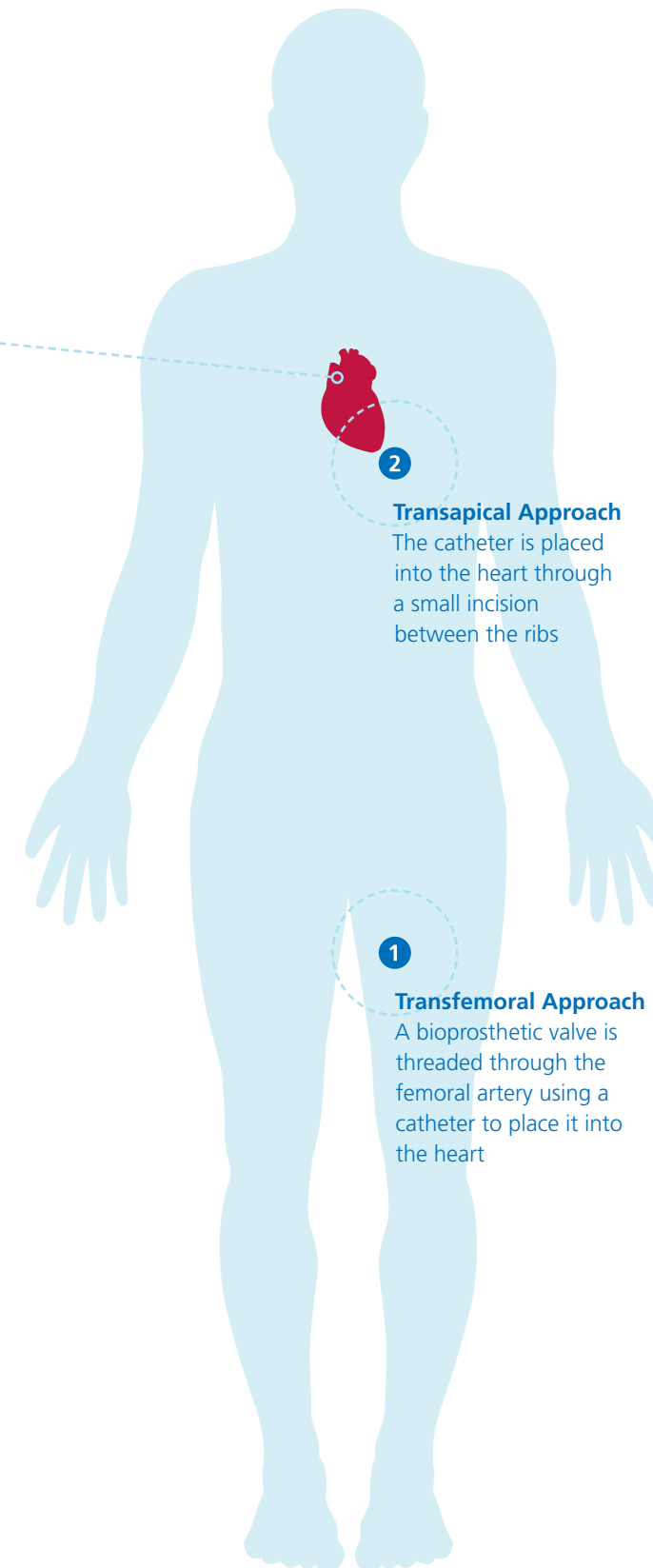
"The challenge that exists with the transfemoral approach is that the individual must have a good vascular system through

which we can access the aortic valve," says Joseph DeRose, MD, Chief, Division of Cardiothoracic Surgery, Montefiore, and Co-Director, TAVR Program, Montefiore Einstein Center for Heart and Vascular Care, Montefiore and Einstein. "When you're dealing with a very sick patient population, this isn't always the case. Many of these individuals are denied surgery because they have constricted or blocked vessels, but we now have an excellent alternative."

Expanded Options for High-Risk Patients

In October 2012, the door was opened for patients with blocked peripheral blood vessels by allowing the catheter to be placed into the heart through a small incision between the ribs (transapical).

"When performing valve surgery, there's always the possibility of complications," says Dr. DeRose. "That risk may be especially high for patients with coexisting conditions or diseases. It's great to know that we now have an option that we can offer these patients. There's no doubt these changes have significantly broadened the pool of potential TAVR candidates."



Transapical Approach

The catheter is placed into the heart through a small incision between the ribs

1

Transfemoral Approach

A bioprosthetic valve is threaded through the femoral artery using a catheter to place it into the heart

Options for TAVR Insertion

During transapical TAVR, a small incision is made between the ribs of the left lower chest. The replacement valve is then inserted directly into the heart and across the diseased aortic valve, where it begins to work immediately.

Success Built on Collaboration

The evolution of TAVR has benefited not only Montefiore's patients, but also the physicians who must work together closely to ensure optimal outcomes.

"One of the strongest features of the TAVR Program is the incredible collaboration that exists between the members of the cardiology and cardiovascular surgery teams and other specialty areas," says Dr. Slovit. "Collaboration isn't just a concept here; it's something we do every day."

"We see a lot of patients who are advanced in years and who have very complex clinical cases," adds Dr. DeRose. "In fact, we've accepted only about a fifth of the patients that we've evaluated for TAVR because they are the ones who would truly benefit from the procedure. That's not to say that we turn the others away. Because of the tremendous expertise that exists within our clinical specialties, we have also been able to offer most patients a conventional low-risk operation."

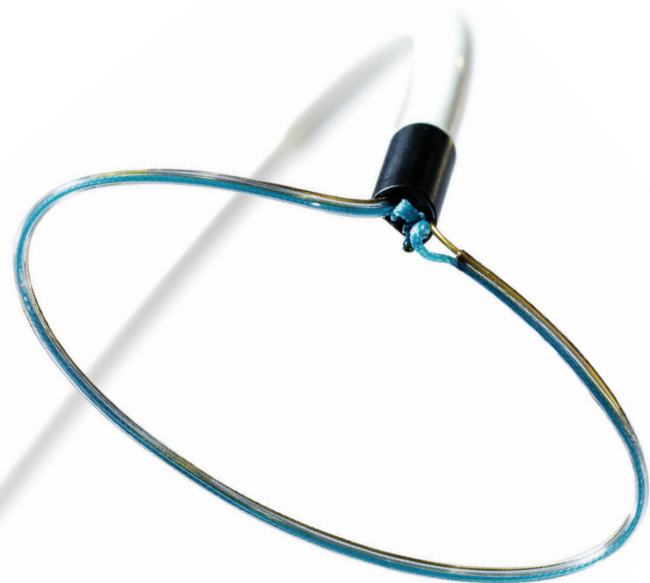
The Future of TAVR

Long recognized for their innovative spirit, the members of Montefiore's TAVR team are already pursuing ways to enhance the program.

"In the short term, we're working to get the word out about our TAVR Program and outcomes," says Dr. Slovit. "Our commitment to our patients means that we are also pursuing new technology and research trials that will help to advance the care we deliver." "There's no doubt that TAVR is one of the decade's most important technological advances," says Dr. DeRose. "I'm really excited about what it means long-term, for both our patients and our field." ❤️



Patients who would like to be considered for TAVR should be referred to Mary Meneses, NP, Clinic Coordinator, Montefiore, at 718-920-6700.



Novel Approach to Left Atrial Appendage Closure Offers Hope for Atrial Fibrillation Patients Who Risk Stroke

With a single suture to the left atrial appendage (LAA), physicians at Montefiore now offer certain patients at high risk of stroke a valuable treatment alternative to blood thinners.

Known as the LARIAT® procedure, this novel approach prevents thromboembolic events through suture ligation of the LAA—an area of the heart where thrombi commonly form in atrial fibrillation (AF) patients. Montefiore is one of the only medical centers in the region to offer this procedure.

“The LARIAT® procedure is ideal for AF patients who have no other options for preventing a stroke,” says Andrew Krumerman, MD, Attending Cardiologist, Montefiore, and Associate Professor, Clinical Medicine, Einstein.

“This would include individuals who cannot tolerate oral anticoagulation (OAC) therapy or who have experienced either contraindications—such as brain or gastrointestinal bleeding—or embolic events while taking OAC medication.”

During the LARIAT® procedure, Montefiore’s cardiac specialists place a magnetic wire inside the left atrial appendage by way of a transseptal puncture. A second magnetic wire is introduced via a percutaneous epicardial approach through the pericardial space and locates the first magnetic wire in the LAA. This creates an endocardial/epicardial magnetic wire rail. A LARIAT® suture is inserted over this rail and placed over the body of the LAA, where it is tied off. This constricts the LAA and ultimately results in occlusion of the appendage. The only item that remains in the patient following the procedure is the suture.

At Montefiore, the LARIAT® procedure is performed in the hybrid operating room by a multidisciplinary team that includes cardiac electrophysiologists, surgeons and imaging specialists who use both echocardiography and fluoroscopic guidance to ensure patient safety and successful outcomes.

Despite its relatively recent introduction, researchers have proven that the LARIAT® procedure can be performed effectively with acceptably low access complications and periprocedural adverse events. In a recent nonrandomized single-center study, researchers found that of 89 subjects who underwent LAA closure using the LARIAT® device, 95 percent had exclusion of their appendage by transesophageal echocardiography. Furthermore, there were no embolic strokes seen in the year of follow-up.

Montefiore is actively recruiting its first patients for this procedure. Prospective candidates include those who are at significant risk of stroke in the setting of AF and cannot tolerate OAC therapy or have experienced contraindications or embolic events while using OAC medication.

Dr. Krumerman emphasizes that patients who have had prior open chest or open heart surgery would not be suitable for the LARIAT® procedure.

“But for those patients who are not eligible for the LARIAT® approach, we can offer equally effective alternatives, such as LAA closure via surgical ligation,” he says. “Our ability to offer patients treatment options that many other centers can’t perform distinguishes Montefiore as a true Center of Excellence.” ❤️



To refer a patient for the LARIAT® procedure, call 718-920-4776.

Novel Mitral Valve Repair Technique Achieving Exceptional Outcomes

As elegant as its namesake, the butterfly procedure combines artistry and clinical innovation to effectively treat patients with mitral valve regurgitation, a condition often characterized by excess tissue in the posterior leaflet of the valve.

This procedure was first performed at Montefiore by Robert E. Michler, MD, Surgeon-in-Chief, Professor and Chairman, Cardiovascular and Thoracic Surgery and Surgery, and Co-Director, Montefiore Einstein Center for Heart and Vascular Care, Montefiore and Einstein. “In the past, the surgical procedure to correct mitral valve regurgitation involved cutting a rigid square, V, or ellipse into the leaflet to remove the excess tissue,” explains Dr. Michler. “The downside was that some patients developed systolic anterior motion (SAM) and required medical management or repeat surgery. This risk is negated with the butterfly approach because it restores the posterior leaflet to its normal height while maintaining its natural geometry.”

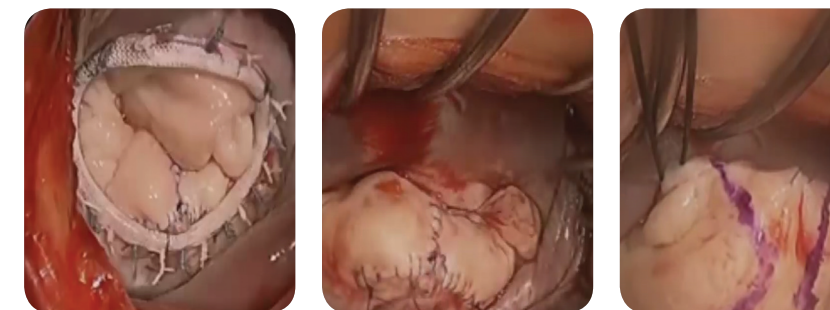
The success of the butterfly procedure depends largely upon a thorough analysis of the diseased valve prior to making any incisions or removing tissue.

“Before I touch the valve, I visualize precisely where to cut a butterfly-shaped segment of abnormal tissue,” says Dr. Michler. “There’s no margin for error with this procedure, so the cut has to be perfect. The technique is akin to plastic surgery on the heart.”

Once the tissue has been removed, the delicate “wings” are sutured together to complete the repair. Patients recover very quickly and are generally out of the hospital within four or five days.

To date, Dr. Michler has performed 30 of these complex operations and achieved a 100 percent success rate. It’s a fact that he attributes in part to his close collaboration with Mario J. Garcia, MD, Chief and Professor, Division of Cardiology, and Co-Director, Montefiore Einstein Center for Heart and Vascular Care, Montefiore and Einstein.

“Dr. Garcia’s expertise in the evaluation of these patients is invaluable,” Dr. Michler says. “He possesses extensive diagnostic experience that helps our surgical team consistently achieve optimal outcomes for these individuals.”



A view of the butterfly procedure

“There are a lot of variables that have to be taken into consideration when evaluating an individual with a heart valve condition,” says Dr. Garcia. “In addition to determining the pathology and significance of the condition, we also have to make a decision regarding treatment—do we repair or replace the valve?”

When Dr. Garcia and his team determine that surgery is the best course of action, he and Dr. Michler convene to map out a treatment plan and subsequently communicate that plan to the referring physician. This collaboration between specialties distinguishes the Montefiore Einstein Center for Heart and Vascular Care from its peers and has contributed to the program’s overall success.

“Our philosophy is very different from that of other centers,” says Dr. Garcia. “Our divisions don’t compete for patients; we work together to do what is best for them.”

The Montefiore Einstein Center for Heart and Vascular Care is widely recognized for its expertise in the area of mitral valve repair and offers the full range of treatment options available. ❤️



To refer a patient for evaluation, please call the Montefiore Einstein Center for Heart and Vascular Care at 718-920-2100.

ODYSSEY Outcomes Trial

Many patients who have sustained acute coronary syndrome (ACS) are not achieving low-density lipoprotein (LDL) levels of <70 mg/dL, despite intensive lipid-lowering therapy.

Regeneron Pharmaceuticals and Sanofi have developed a novel lipid-lowering therapy, SAR236553/REGN727, to address the need for cholesterol-lowering in secondary prevention. ODYSSEY Outcomes is a randomized, double-blind, placebo-controlled phase III study with a composite endpoint consisting of cardiovascular death, nonfatal myocardial infarction, fatal and nonfatal ischemic stroke, and unstable angina requiring hospitalization. It is an international multicenter study, with a goal of studying 18,000 patients. Montefiore is a top-ranked site (90th percentile of 255 sites) for this important study.

SAR236553/REGN727 is a fully human monoclonal antibody that binds PCSK9 (proprotein convertase subtilisin kexin type 9). Typically, PCSK9 binds the LDL receptor and causes its degradation. By keeping it intact with the PCSK9 antibody, this leads to increased clearance of LDL from the blood. The antibody is self-administered from a pre-loaded injector pen just twice a month and has slow absorption over five to seven days. Two key publications in the *New England Journal of Medicine* established the best concentration of the drug and its effect on LDL-lowering in combination with a statin.

Patients are eligible if they are above age 40, have experienced an ACS in the past year and are on intensive statin therapy. This is defined as atorvastatin 40 or 80 mg, rosuvastatin 20 or 40 mg, or other nonstatin lipid-modifying agents. A patient could be off of statin, if intolerant, but must be taking an alternative such as ezetimibe, fenofibrate, fish oil or niacin.

Patients enrolling in the study are followed prospectively for approximately five years and compensated for their visits. The most common adverse event reported thus far is rash at the injection site, according to the Duke Clinical Research Institute (DCRI), and any adverse events are being monitored closely by our site and by DCRI.

Anna Bortnick, MD, the Montefiore team leader, describes her group's effort as follows: "Our Montefiore team meets almost daily to complete forms, review our prospective and enrolled patients, and problem-solve. Our population in the Bronx is

disproportionately affected by early coronary artery disease. We feel that we are offering patients the best in innovative clinical research by having the ODYSSEY Outcomes trial at Montefiore. Our patients are excited to participate in a study of cutting-edge therapy. They like being seen by our study team on a regular basis and feel like it improves their care. Some of our patients using canes and walkers show up to appointments even in bad weather because they feel a strong commitment to the study." ♥



Additional information is available at www.odysseytrials.com/web/ and on www.clinicaltrials.gov. If you have any patients that you would like considered for the study or have any questions about the study, please email Dr. Bortnick at abornic@montefiore.org or call 718-904-2573.

RESEARCH UPDATE

Stem Cell Therapy for Heart Failure

STOP-HF (Sdf-1 plasmid Treatment for Patients with Heart Failure) is a multicenter trial sponsored by Juventas Therapeutics that aims to assess the safety and efficacy of JVS-100, a novel stem-cell therapy, in improving symptoms and quality of life in patients with heart failure.

"The hope is that this therapy will repair damaged tissue through the recruitment of circulating stem cells to the site of injury, prevent ongoing cell death and restore blood flow," says Auris Browne, MD, Director of Clinical Trials and Regulatory Affairs, Division of Cardiology, Montefiore. "If it does this successfully, then it would be a valuable addition to the treatment portfolio for heart failure patients."

For the STOP-HF study, Montefiore is actively seeking patients with a known history of systolic dysfunction, prior myocardial infarction (MI) and who are free of cancer, verified by an up-to-date, age-appropriate cancer screening. Prospective subjects must also be able to walk the hallways continuously for six minutes or 400 meters. Study participants will be randomly selected to receive a single 15 or 30 mg dose of JVS-100 or matching placebo that is injected directly into the left ventricle.

To date, Montefiore has enrolled 13 patients for evaluation, and four have met the criteria for participation in the study. Physicians who would like to refer a patient for the STOP-HF study should contact Auris Browne at 718-920-8576. ♥

Sutureless Valve Replacement

Montefiore recently began recruiting patients to participate in a multi-site trial evaluating the safety and efficacy of the Perceval S Sutureless Heart Valve (PERCEVAL valve). The PERCEVAL valve is a bioprosthetic heart valve developed by Sorin Biomedica Cardio S.r.l. that is designed for conventional cardiac surgery techniques using an implant, but without the need for suturing the valve to the aortic annulus.

"A key benefit of this valve is that it eliminates the need for sutures through the annulus and suture knotting," says Roger Swayze, RN, BSN, MBA, Director of Clinical Research and Regulatory Affairs, Cardiovascular and Thoracic Surgery and Surgery, Montefiore. "This reduces the risk of tearing the aortic annulus and wall and damaging the bundle of His," he says. "It also reduces the risk of embolizing foreign material being released into the vascular system."

Other prospective benefits of the PERCEVAL valve are reduced aortic cross-clamp times with a subsequent overall reduction of surgical timing and a reduction in related risks.

To be considered for a PERCEVAL valve, prospective patients must be over 18 years of age and candidates for isolated replacement of their native aortic valve or a previously implanted prosthetic aortic valve. Study subjects must be available for postoperative

evaluations at 30 days, three to six months and then annually for five years.

Patients who are prospective candidates for the PERCEVAL valve should be referred to Robert E. Michler, MD, Surgeon-in-Chief, Professor and Chairman, Cardiovascular and Thoracic Surgery and Surgery, and Co-Director, Montefiore Einstein Center for Heart and Vascular Care, Montefiore and Einstein, at 718-920-2100. ♥

Montefiore Participates in New Cardiac Trials

Research has long played a pivotal role in the advancement of cardiac care at Montefiore. Members of the Montefiore Einstein Center for Heart and Vascular Care regularly participate in prestigious federal and industry-sponsored trials and have played a role in major clinical breakthroughs that have helped define Montefiore's place as a pioneer in the field.

Now, Montefiore is building upon this tradition with groundbreaking clinical studies. ♥

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Enhancing Heart Failure Care Through Remote Technology

A device that is roughly the size of a box of chocolates is helping Montefiore cardiologists and nurses enhance care and improve outcomes for patients with congestive heart failure.

This technology, known as Telehealth, is used by patients in their homes to measure key vital signs such as blood pressure, oxygen saturation and weight. The data is transmitted electronically over the patient's phone line to members of Montefiore's Telehealth Program team, who use it to make adjustments to the individual's care.

"Telehealth is ideal for people who are hospitalized frequently for heart failure," says Irina Sigal, RN, BSN, CDE, Manager, Telehealth Program, Montefiore. "It allows our nurses and doctors to virtually 'see' patients on a daily basis and make real-time changes to diet or medication that can improve their quality of life and long-term outcomes. In the past, this level of care could be achieved only through hospitalization or in-home visits."

"I have found Telehealth to be particularly useful in patients with advanced heart failure," says Snehal Patel, MD, Attending Cardiologist, Department of Medicine, Montefiore, and Assistant Professor, Medicine, Einstein. "When dealing with these patients, finding a balance between their blood pressure limits and medications can be challenging. Now we have the ability to check their weight and blood pressure daily, which lets us push the limits of the therapy we can give."

According to Ms. Sigal, education plays a critical role in patient compliance and disease management.

"What I find is that many of these patients have a poor understanding of their disease," she says. "For example, they may not understand why weight gain is a problem. But what they don't realize is that weight gain can be a sign of fluid retention, which makes their already-weakened heart work

even harder. With Telehealth, we can catch this quickly and get them on an appropriate dose of diuretic. Once patients are aware of the importance of this information and its impact on their condition, they are more willing to adhere to daily check-ins."

In addition to monitoring vital signs, Telehealth can also be programmed to have a personalized dialogue with patients in either English or Spanish. Some patients may receive reminders to take their medication, while others receive daily tips related to their diet.

"The Telehealth system is programmed to ask patients questions that are specific to their condition," says Ms. Sigal. "If a patient responds to a question in a way that causes concern, we will call that individual and conduct a more detailed assessment."

She says that Telehealth has been well-received by patients and healthcare providers.

"Many patients tell me that they like the security that Telehealth provides them and the fact that it empowers them to take better care of themselves," says Ms. Sigal.

Telehealth is Medicaid-endorsed for use by patients with chronic diseases. ❤️

i For more information about Telehealth or to refer a patient, please call Irina Sigal at 718-405-4528 or Montefiore Home Care intake at 718-405-4800.

Legacy in Education and Research

Introducing the James and Ruth Scheuer Endowment



James Scheuer, MD

For more than four decades, James Scheuer, MD, has been an outstanding researcher and invaluable leader in Montefiore's Division of Cardiology. His distinguished history of clinical and academic leadership has proven vital to building the foundation for today's Montefiore Einstein Center for Heart and Vascular Care. Please join us in honoring his legacy by making a gift to the James and Ruth Scheuer Endowment.

This endowment will focus on Dr. Scheuer's passion, the development of exceptionally talented young physicians. Gifts to the endowment will help provide specialized training and experience in research that will enable the recipients to make significant contributions throughout their careers and advance the field of cardiovascular health.

To make your online gift to the James and Ruth Scheuer Endowment, visit www.givetomontefiore.org/scheuerendowment or send your gift to: Sheila Wolfinger, Director of Development, Office of Development, 111 East 210th Street, Bronx, New York 10467. ❤️

Introducing the Lari Attai, MD, Cardiothoracic Surgery Residency Education Fund



Lari Attai, MD

The Montefiore Einstein Center for Heart and Vascular Care is committed to educating the next generation of surgical leaders. Since its inception more than 50 years ago, the Center has produced more than 175 graduates, many of whom are leaders in medical institutions around the world.

At the 50th Anniversary Celebration on December 16, 2013, we introduced the Lari Attai, MD, Cardiothoracic Surgery Residency Education Fund. As the cost of quality residency education continues to rise, MECHVC remains deeply committed to producing high-achieving graduates. Donations to this fund will help underwrite the costs of the residency program.

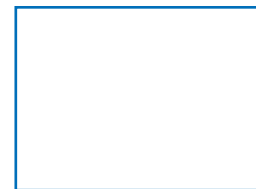
"Giving back has been one of the highlights of my 55 post-graduate years," says Lari Attai, MD, PGY, 50. Montefiore is a special place, where we learned, grew and developed as physicians. Join me in giving back so that this program that provides future generations of physicians with an invaluable surgical foundation can move forward."

Your gift will go directly to support this fund. To give to the fund, please contact Kristin Waller-Donovan at 718-920-6629 or kwaller@montefiore.org. ❤️



Montefiore

The University Hospital for Albert Einstein College of Medicine



**Montefiore Einstein Center
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