Mount Sinai Heart

SPECIALTY REPORT | WINTER 2017

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Mount Sinai Heart

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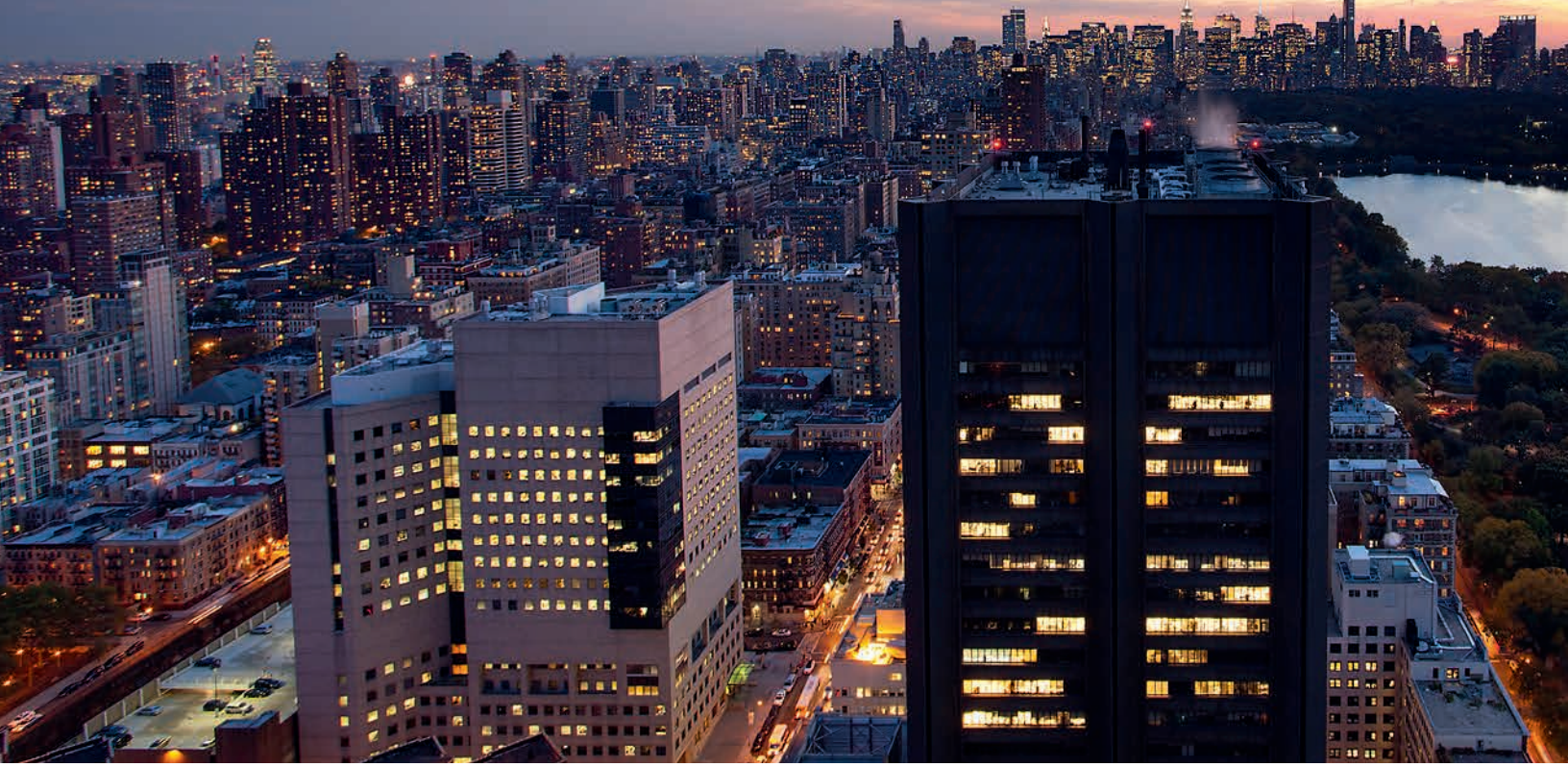
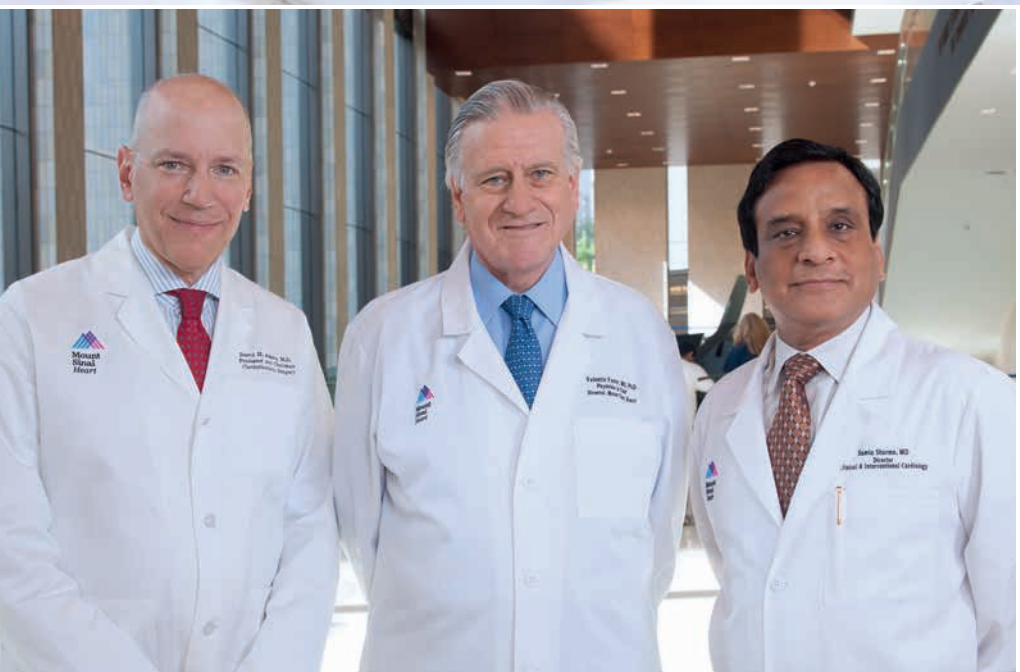




The Mount Sinai Hospital, on the Upper East Side of Manhattan, had a new addition in 2016: The Lauder Family Cardiovascular Ambulatory Center, a unit of Mount Sinai Heart, under the leadership of founding Director Valentin Fuster, MD, PhD (center); David H. Adams, MD, Chair of Cardiovascular Surgery (left); and Samin K. Sharma, MD, Director of Clinical and Interventional Cardiology.

A LETTER FROM THE DEAN

Dennis S. Charney, MD, *Anne and Joel Ehrenkranz Dean, Icahn School of Medicine at Mount Sinai, and President for Academic Affairs, Mount Sinai Health System*

Cardiovascular disease is the deadliest in the world. Each year, it kills 17 million people and costs more than $500 billion to treat. Through Mount Sinai Heart, established in 2006, the Mount Sinai Health System is leading the charge to address this global problem.

Valentin Fuster, MD, PhD, the founding Director of Mount Sinai Heart and a preeminent cardiologist of our generation, envisioned a union of internationally renowned clinical and research experts providing exceptional care for heart disease patients. Today, Mount Sinai Heart is among the world's leading centers for cardiovascular medicine and advanced diagnostic and therapeutic technologies.

Our multidisciplinary effort brings together the expertise of the Icahn School of Medicine at Mount Sinai and The Mount Sinai Hospital. We offer state-of-the-art imaging and health care facilities, scientists in advanced laboratories to conduct research in cutting-edge areas like genomics, and leading programs in postgraduate medical education. Our mission is to improve the heart health of patients from the local, regional, and global communities. In global health, Dr. Fuster has created a program to teach heart-healthy habits to preschool children around the world.

In this report, you will learn about the following extraordinary accomplishments of our heart team:

- Under the leadership of David H. Adams, MD, our cardiovascular surgery program has grown to become one of the largest in the country, anchored by a mitral valve repair reference center that has achieved worldwide acclaim.

- The Mount Sinai Hospital's 20,700-square-foot Lauder Family Cardiovascular Ambulatory Center opened with the generous support of the Lauder family and donated in honor of Dr. Fuster, is led by Joseph M. Sweeny, MD, Medical Director.

- Some of the nation's best outcomes are achieved by The Mount Sinai Hospital's Cardiac Catheterization Laboratory, led by Samin K. Sharma, MD, who holds New York State's prestigious two-star safety rating for PCI.

- The coronary bypass team, led by John D. Puskas, MD, has been a driving force in the adoption of multiple arterial grafts as an alternative to saphenous vein grafts in CABG and has led the development of advanced techniques for minimally invasive and off-pump CABG.

- Vivek Y. Reddy, MD, is spearheading the development of new technology for catheter ablation for atrial fibrillation and was the first in the nation to implant a miniature leadless pacemaker into a patient's heart.

- The Vascular Medicine section, led by Jeffrey W. Olin, DO, has been in the forefront of noninvasive imaging for the evaluation of vascular disease and is an international leader in fibromuscular dysplasia.

- The Division of Vascular and Endovascular Surgery, under the guidance of Michael L. Marin, MD, and Peter Faries, MD, performed 2,309 surgeries in 2015, with low rates of mortality.

- The Center for Aortic Disease draws on the expertise of Allan S. Stewart, MD, and of Paul Stelzer, MD, a pioneer in the Ross procedure and other complex surgeries.

- Jagat Narula, MD, PhD, MACC, an expert on clinical and experimental imaging, has built a wide range of imaging services for Mount Sinai's physicians and researchers.

- In 2016, our Advanced Heart Failure and Transplantation Program, under clinical leaders Anelechi Anyanwu, MD, and Sean P. Pinney, MD, performed 30 transplants—the highest volume ever, with a one-year survival rate of 87 percent.

- In translational research, Roger Hajjar, MD, who leads the Cardiovascular Research Center, is pioneering new treatment modalities for patients with advanced heart failure.

- The Center for Medical Devices, led by Julie Swain, MD, has created a powerful database of 8,500 patients, and the Center for Interventional Cardiovascular Research and Clinical Trials, led by Roxana Mehran, MD, conducts research that spans observational registries and trials.

- Jonathan L. Halperin, MD, chaired the ACC/AHA committee that sets national guidelines for cardiovascular care. Mary A. McLaughlin, MD, directs an outstanding cardiac rehabilitation program. Martin Goldman, MD, a national expert in echocardiography, heads a training program for cardiology fellows considered among the very top in the nation.

We believe we provide compassionate, seamlessly coordinated patient care with unrivaled education and research. The narratives in this report demonstrate the skill, commitment, and creativity of Mount Sinai Heart's world-leading clinicians and researchers.

ABOUT THE DIRECTOR

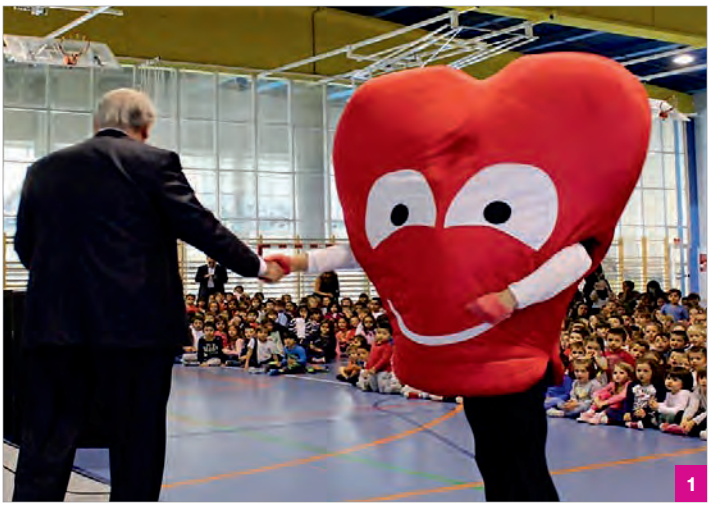
Valentin Fuster, MD, PhD, *Director of Mount Sinai Heart and Physician-in-Chief of The Mount Sinai Hospital*

Valentin Fuster, MD, PhD, serves The Mount Sinai Hospital as Physician-in-Chief and Director of Mount Sinai Heart.

The many positions he has held include President of the American Heart Association; President of the World Heart Federation; and member of the U.S. National Academy of Medicine, where he chaired the Committee for the document "Promotion of Cardiovascular Health Worldwide." He is presently Co-Chair of the Committee on Global Health and the Role of the United States, which was established to advise the new U.S. President, and is a member of the European Horizon 2020 Scientific Panel of Health. He was also a council member of the National Heart, Lung, and Blood Institute and was President of the Training Program of the American College of Cardiology.

Dr. Fuster has been named Doctor Honoris Causa by 33 universities. He is an author on more than 1,000 scientific articles. He is Editor in Chief of the journal *Nature Reviews in Cardiology* and of the *Journal of the American College of Cardiology*, the ACC's flagship publication and the main American source of clinical information on cardiovascular medicine. His research into the origin of cardiovascular events, which has contributed to improved treatment of heart attack patients, was recognized in 1996 by the Prince of Asturias Award for Technical and Scientific Research, the highest award in Spanish-speaking countries. And in June 2011, he was awarded the Grand Prix Scientifique of the Institute of France for his translational research into atherothrombotic disease.

Dr. Fuster is the only cardiologist to have received the highest awards for research from the three leading cardiovascular organizations: the American Heart Association (Gold Medal and Research Achievement Award), the American College of Cardiology (Living Legend and Life Achievement Award), and the European Society of Cardiology (Gold Medal). In addition, in May 2014, King Juan Carlos I of Spain granted Dr. Fuster the title of Marquis for his "outstanding and unceasing research efforts and his educational outreach work."



1. Valentin Fuster, MD, PhD, speaks to elementary school children about heart-healthy habits.

GLOBAL HEALTH

Promoting Cardiovascular Health and Compassionate Care Around the World

Valentin Fuster, MD, PhD, *Director of Mount Sinai Heart and Physician-in-Chief of The Mount Sinai Hospital*

In Rural Kenya, Seeking Strategies to Manage Hypertension

A grant from the National Heart, Lung, and Blood Institute is funding a program evaluating novel strategies to optimize hypertension management in rural western Kenya. Working with Dr. Fuster, the Principal Investigator is Rajesh Vedanthan, MD, Associate Professor of Population Health Science and Policy and Associate Professor of Medicine (Cardiology) at the Icahn School of Medicine at Mount Sinai. Cardiovascular disease (CVD) is the leading cause of death among adults older than 30 in sub-Saharan Africa. The prevalence of hypertension, a major risk factor for CVD, is increasing in the region, exerting a significant epidemiologic and economic burden. Without adequate control of hypertension, these health and economic burdens will increase drastically in the decades ahead. Well-established and evidence-based interventions to manage hypertension exist; however, treatment and control rates are low. These issues are explored in the Kenya project.

A critical component of hypertension management is the ability of affected individuals to have sustained access to effective clinical services. In partnership with the government of Kenya, AMPATH—the Academic Model Providing Access to Healthcare, under the U.S. Agency for International Development—is expanding its clinical scope of work in rural western Kenya to include hypertension and other chronic diseases. However, linking and retaining individuals with elevated blood pressure to the clinical-care program has been difficult. Thus, the overall objective of Dr. Fuster's project is to use a multidisciplinary approach to address this challenge. Specifically, the project is testing the hypothesis that community health workers (CHWs)—equipped with a tailored behavioral communication strategy and a smartphone-based tool linked to an electronic health record—can increase linkage and retention of hypertensive individuals to a clinical-care program and thereby significantly reduce blood pressure among these patients.

- The first aim of the project is to identify facilitators and barriers to linking individuals with high blood pressure to a hypertension care program, using innovative and novel qualitative research techniques.
- The second aim is to evaluate the effectiveness of CHWs equipped with these tools and techniques in improving

2. Rajesh Vedanthan, MD, is a lead investigator of the Kenya project, which is part of a larger focus on health in developing nations.

linkage to care and reducing blood pressure among hypertensive patients, by conducting a three-arm cluster randomized trial. The trial is comparing CHWs with standard training on recruitment of individuals, CHWs with an additional tailored behavioral communication strategy, and CHWs with a tailored behavioral communication strategy who are also equipped with smartphones linked to the electronic health record.

- A third aim of the project is to evaluate the incremental cost-effectiveness of each intervention arm of the cluster randomized trial, both in terms of costs per unit decrease in blood pressure and costs per reduction in CVD risk.

A multidisciplinary team of investigators with diverse and complementary expertise is conducting the research. This project aims to add to existing knowledge on scalable and sustainable strategies for optimizing control of hypertension and other chronic diseases in low- and middle-income countries. ■

3. A clinic in rural western Kenya, where a project is evaluating tools and strategies to link patients with hypertension management programs.

Mobile App to Promote Cardiovascular Health: The Circle of Health

Valentin Fuster, MD, PhD, has developed a free mobile application called The Circle of Health to empower individuals around the globe to take action to assess and enhance their daily overall heart health. Cardiovascular diseases are the number one cause of mortality in the world. Dr. Fuster created The Circle of Health to promote cardiovascular health worldwide and reduce the epidemics of coronary artery disease, heart attack, and stroke.

Dr. Fuster and the Icahn School of Medicine at Mount Sinai in New York collaborated with the Fundación Pro CNIC in Spain to develop the mobile app, now internationally available in English and Spanish.

Cardiovascular diseases are acquired and largely preventable. The vast majority arise due to one or more of six risk factors that can be prevented or reduced with daily lifestyle and behavior modifications. These risk factors are high cholesterol and diabetes (chemical), obesity and high blood pressure (physical), and smoking and lack of exercise (behavioral).

Using the mobile app, users learn directly from Dr. Fuster about the six risk factors, how to prevent or better manage them, and how to live healthier and longer lives. It helps adults to properly measure, prevent, fight, and reduce their risk factors.

The mobile app has a unique interactive circular format, which creatively incorporates video, audio, and educational graphics. It comprehensively evaluates users' health through an initial questionnaire to establish their baseline cardiovascular health. Then it empowers them with the health information and prevention tips they need to succeed in addressing their risk factors, providing users with weekly and monthly motivation to establish good habits and reduce bad ones, as well as challenges to get more physically active.

Nearly two billion people in the world have smartphones. Given the growing popularity of smartphones and tablets and the mutually growing global threat of cardiovascular diseases, Dr. Fuster believes there is no better way to reach people than via their mobile devices to prevent and reduce the risk factors for heart disease. ■

SI! The Salud Integral Program Promotes Cardiovascular Health in Childhood

The accumulation of preclinical substrate in atherosclerotic disease begins at early ages. Its development largely results from nonheart-healthy behavior that determines exposure to risk factors. Low exposure of adults to risk factors is associated with a decrease in cardiovascular death, increase in survival, and improved quality of life.

Population studies have revealed the importance of health promotion, primordial prevention (preventing the adoption of risk factors), and primary prevention (combining interventions aimed at modifying risk factors to prevent an initial cardiovascular event). Particularly worrying are trends that show not only increased levels of obesity and diabetes mellitus in populations but also the development of these diseases at younger and younger ages. These trends underline the need for health-promotion strategies that include primordial and primary prevention programs throughout an individual's life.

During recent decades, the main cardiovascular risk factor in both adults and children has been identified as obesity and associated factors, such as diabetes mellitus and hypertension, a consequence of poor nutrition and limited physical activity. Recently, results have been published on the incidence and prevalence of childhood obesity in the United States, with 12.4 percent of preschool-aged children obese and 14.9 percent overweight. Obesity is more prevalent at lower socioeconomic and education levels.

Data obtained through noninvasive imaging studies have shown that exposure to cardiovascular risk factors during childhood and adolescence is associated with a significant increase in subclinical atherosclerosis during adulthood. These studies have shown high prevalence of the main cardiovascular risk factors in childhood and, moreover, that these risk factors are potentially modifiable.

We believe that there is an urgent need to implement high-quality health-education programs for children (both for families and in the school environment), to help them to adopt heart-healthy lifestyles as they grow to adolescence and adulthood. Thus, a total health program called SI! (Salud Integral, or comprehensive health) was designed to promote heart-healthy behaviors in children aged 3 to 5. Using the school environment and the appeal of *Sesame Street* and its tradition of high-impact educational programs, this program is introducing a conceptual change in disease prevention by moving toward health promotion. The school environment plays a fundamental role in this type of intervention, given that it provides an appropriate environment for evaluating its effectiveness in controlled conditions.

Strategies for primordial and primary prevention of risk factors.

The most effective interventions introduced in schools are those that involve families and have among their objectives behavioral markers such as changes in knowledge, attitudes, and habits. Following this strategy, a first randomized study was performed in Bogotá, Colombia, including 1,216 children, 928 families, and 120 teachers who were observed for three years. Treatment schools received a six-month intervention of 70 hours to promote cardiovascular health. The results were impressive, and significant improvements were found in all indexes of knowledge, attitude, and habits in the schools that received the intervention. These differences were maintained for 36 months after the intervention, indicating the persistence of heart-healthy habits that are acquired at this age.

The SI! program takes into consideration the main cardiovascular risk factors and follows a total health-promotion approach that goes beyond obesity prevention. It aims to establish healthy lifestyles at an early age by intervening in four basic interrelated components: the human body, physical activity,

4. In Bogotá, Colombia, the SI! (Salud Integral) program educated schoolchildren on cardiovascular health and measured changes in behavioral markers such as knowledge, attitudes, and habits.

diet, and—expanding on the original design—management of emotions as a fundamental factor in preventing the use of harmful substances, such as tobacco, alcohol, and drugs. These components are studied across three dimensions: knowledge, attitudes, and habits. Thus, individuals go from understanding the component (knowledge) to its practice (attitude), and to the acquisition of a pattern of behavior that is maintained over time (habit).

The program employs didactic material and educational strategies, such as featuring the *Sesame Street* characters, which are used in the projects in Colombia and Spain. Moreover, the intervention is continually appraised by specialists in medicine, childhood development, and communication to improve the strategies applied. To demonstrate that the effect of the intervention is persistent—an important point—the program is evaluated at various stages by measuring health determinants, which include a range of indicators, from basic changes in behavior (knowledge, attitude, habits) to intermediate clinical markers (such as body mass index). Prevention studies aiming at 20 years of follow-up currently involve some 50,000 children internationally.

The final objective of any health-promotion program is a reduction in the mortality and comorbidity of a population, an increase in the quality of life during adulthood, and a decrease in associated health care costs. By acting on the behavior of preschool children, we hope to avoid the acquisition of habits that expose them to cardiovascular risk factors at a young age. Even modest improvements in the cardiovascular risk profile will have a marked impact on the adults of the future, given the prevalence of the problem and the developmental time of the disease. ■

FAMILIA Project Seeks to Create a "Culture of Health" For Children in Harlem

Heart disease is the leading cause of death for both men and women in the United States. On average, one in every four Americans dies from heart disease. Every minute, there is a death from a heart disease–related event in the country, and a heart attack every 43 seconds.

In 2014, Valentin Fuster, MD, PhD, and Mount Sinai Heart were awarded a $3.8 million American Heart Association (AHA) grant for promoting cardiovascular health among children ages 3 to 5 and their caregivers in high-risk communities in New York City. The grant was part of a $15 million AHA program in which Mount Sinai Heart was named one of four Strategically Focused Prevention Research Network Centers. Our research supports the AHA's goal of improving the cardiovascular health of all Americans by 20 percent and reducing deaths from cardiovascular diseases and stroke by 20 percent by 2020.

Almost one-third of adults and children in the United States are obese, with the highest rates affecting the Hispanic and African American communities in New York City and elsewhere. Obesity is a major cause of heart disease, stroke, type 2 diabetes, and other preventable diseases.

That is why Mount Sinai Heart created the new FAMILIA Project for early-childhood intervention. This four-year project, launched in fall 2015, aims to reduce the epidemic of childhood obesity and better clarify how the intersection of a child's behavior, environment, and genetics may lead to heart disease, while refining our future prevention techniques. The goal is to reduce each child's future risk of obesity, heart attack, stroke, and type 2 diabetes by creating a family-based "culture of health."

This family-based health-education and health-assessment project is enrolling 600 children ages 3 to 5 in participating New York City preschools, along with 1,000 of their caregivers, in high-risk communities of Harlem. Mount Sinai Heart's research team will measure the impact of early-childhood heart-health education in this population. The ultimate hope of the research team is to instill heart-healthy habits among children and their parents or caregivers to potentially change behavior, reduce obesity, and prevent cardiovascular diseases for generations to come.

The FAMILIA Project in Harlem builds on the success of Dr. Fuster's similar programs in Kenya; Bogotá, Colombia; and throughout Grenada and Spain, where he has shown that nearly 5,000 young children can maintain a healthy weight over time and learn long-lasting heart-healthy habits. The AHA recognized Dr. Fuster's findings as among the top 10 research advances of 2013.

FAMILIA Intervention Programs include:

- Child Intervention
- Adult Intervention
- Peer-Group Intervention
- Individual Intervention ■

5. In fall 2015, Valentin Fuster, MD, PhD, launched the early childhood heart health intervention program in select New York City preschools, in collaboration with the American Heart Association, the federal Head Start program, and the Sesame Workshop. Above, his Muppet counterpart, Dr. Valentin Ruster, with friends.

Grenada Heart Project Builds a Model of CVD Prevention Amid Westernization

The Grenada Heart Project resulted from conversations between the principal investigator, Valentin Fuster, MD, PhD, and a panel of representatives from the United Nations, who were concerned by the dramatic increase in cardiovascular risk factors sweeping low- and middle-income countries and sought a cost-effective model for CVD prevention.

Located in the Caribbean Sea, the island nation of Grenada has a population of 111,219, and the majority are of African descent. The island has recently undergone a process of "westernization," and it now has rates of hypertension and type 2 diabetes mellitus that surpass those seen in the United States. In contrast, the paradoxically low prevalence of CVD supports the view that the country is undergoing an obesity-related "risk transition." This phenomenon usually results when there is a disproportionate increase in obesity-related diseases due to an excessive intake of fat and alcohol, generally in the context of a rapid westernization that particularly affects middle-aged individuals. In the case of a country such as Grenada that has limited resources, the potential increase in CVD combined with a high rate of infectious diseases saddles the country with a "double burden" of disease, which could have catastrophic consequences for population health. Although the risk transition is almost complete, the transition corresponding to increased cardiovascular morbidity and mortality remains to be seen, which presents a rare opportunity for the role of prevention in achieving cardiovascular risk-factor control and eliminating the future burden of cardiovascular disease.

The Grenada Heart Project conducted an observational study of 2,827 adults randomly selected from the national electronic voter list of Grenadians aged 18 to 70. The aim was to assess the clinical, biological, and psychosocial determinants of cardiovascular health in Grenada in order to develop and implement a nationwide cardiovascular health-promotion program. The study, in collaboration with Dr. Fuster and led by Sameer Bansilal, MD, Assistant Professor of Medicine (Cardiology) at the Icahn School of Medicine at Mount Sinai, assessed behavioral risk factors, anthropometric measures, blood pressure, point-of-care testing for glucose and lipids, EKGs, ankle-brachial index, and self-reported personal and family history of cardiovascular disease and related risk factors. Analysis of the data revealed prevalence rates of obesity, hypertension, and diabetes significantly exceeding those seen in the United States.

A follow-up study, called Grenada Heart Project-CHANGE (Community Health ActioN to EncouraGe Healthy BEhaviors), is a randomized controlled trial of 402 individuals from the original 2,827, selected because they had one or more cardiac risk factors. The project studied the effectiveness of a peer-support strategy in modifying the behavior of healthy individuals at risk of CVD. The study's community-based intervention aimed to promote positive behaviors and focus more on what creates health rather than what prevents sickness. In this program we tested the impact of promotion of healthy lifestyle behaviors through peer motivation, tracking a score called Fuster-BEWAT, which accounts for blood pressure, exercise, weight/BMI, alimentation (fruit and vegetable intake), and tobacco use.

This study, completed in June 2016, demonstrated that the active participation of health care professionals is not always required. In this case, participants were divided into peer groups with the aim that they would help each other achieve their goals, such as consuming a diet rich in fruits and vegetables and low in salt, or increasing exercise. This model has allowed implementation of a local monitoring system that has proved to be efficient, particularly in environments with limited resources. ■

Cardona Program Fosters Health in an Urban Population

Developed from the heart study conducted by Mount Sinai's Valentin Fuster, MD, PhD, and colleagues on the island of Grenada, the Cardona Integral Fifty-Fifty program aims to improve the overall health of adults aged 25 to 50 by helping them improve their health habits and manage their main risk factors for cardiovascular disease: excess weight and obesity, a sedentary lifestyle, smoking, and hypertension. The program is taking place in various towns in Spain in collaboration with the Spanish Federation of Municipalities and Provinces and is derived from the Science, Health and Education Foundation initiative, fostered by Dr. Fuster, and Spain's Agency of Food Safety and Nutrition, within the framework of the NAOS (nutrition, physical activity, obesity prevention, and health) strategy and of the Observatory of Nutrition and Study of Obesity.

Fifty-Fifty consists of training and motivational workshops, with all participants in the program receiving 10 hours of instruction directed at promoting healthy life habits. During the subsequent 12 months, this training is accompanied by role-playing aimed at promoting behavioral changes and providing participants with the ability to develop skills that transcend simple knowledge to help them better themselves.

In Cardona, Spain, the Fifty-Fifty program expands on the pilot study in Grenada and includes an ambitious plan to promote physical activity in an urban population. The idea is to incorporate healthy habits into daily life through an environment that facilitates and promotes these habits. By promoting an active lifestyle, the project encourages individuals to make healthy decisions about how they move around, what they eat, and how they interact with their surroundings. The program transcends the health care field and includes, for example, projects aimed at recovering natural environments with the participation of volunteers from Cardona and integration of unemployed local residents into the project according to their abilities. The Cardona Integral Fifty-Fifty program can serve as a model that inspires the creation of healthy towns that help their inhabitants choose and maintain healthy ways of life. ■

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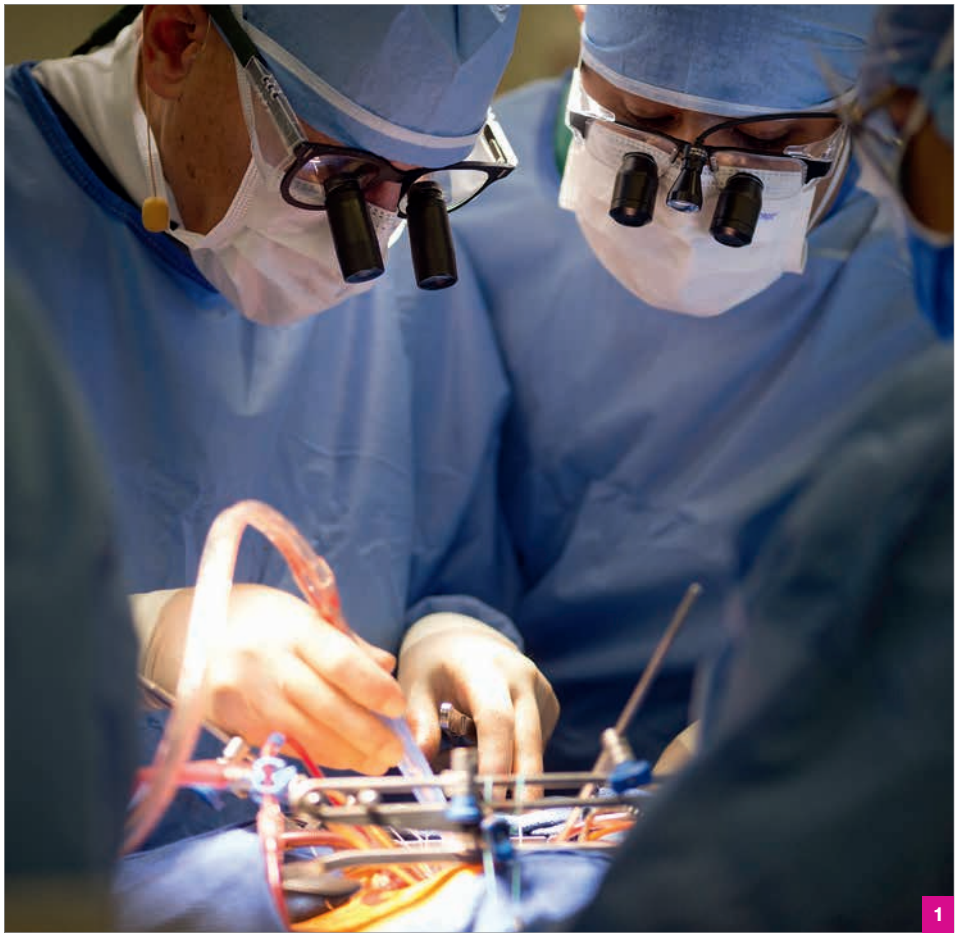
Team

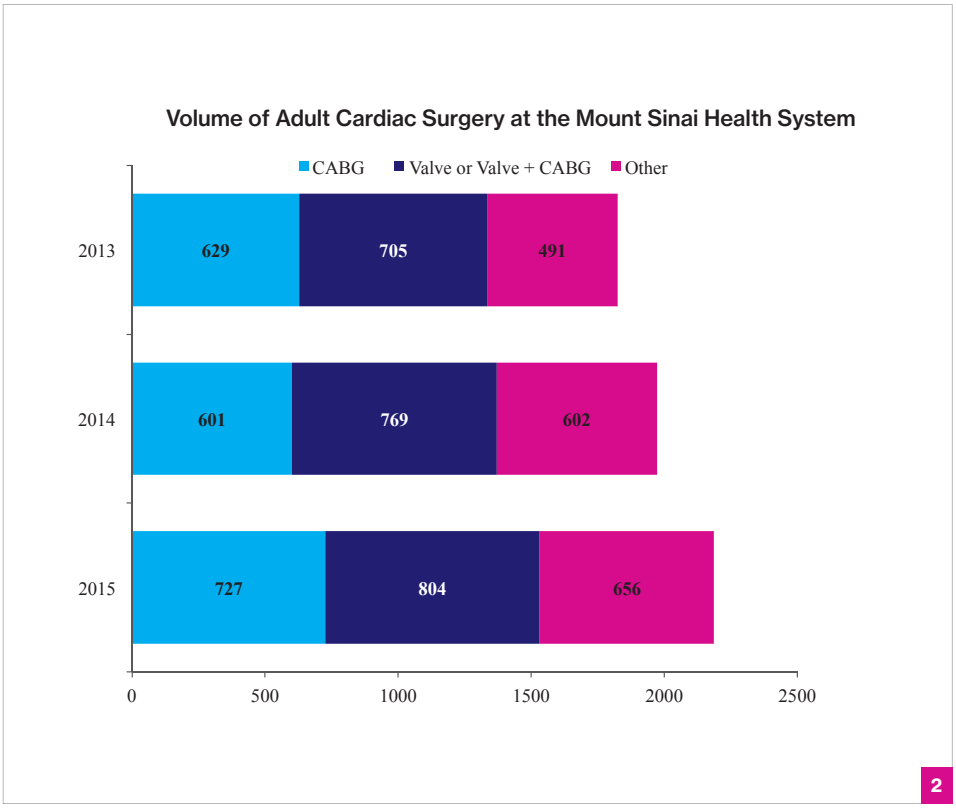
From left: Chiara Giannarelli, MD, *Co-Investigator*; **Monali Fatterpekar, MD,** *Project Coordinator*; **Andrea Clarke-Littman,** *Administrative Secretary*; **Briana Cortez,** *MSGH, Program Coordinator*; **Rodrigo Fernandez-Jiménez, MD**, *AHA Cardiology Fellow*; **Zahi Fayad, MD,** *Principal Investigator*; **Valentin Fuster, MD, PhD,** *Principal Investigator*; **Sameer Bansilal, MD,** *Co-Investigator*; **Jacqueline Latina, MD,** *AHA Cardiology Fellow*; **Alexa Schulman,** *Project Coordinator*; **Liane Pei,** *Director, Research Administration, Cardiology*; **Risa Jaslow, RDN,** *Project Manager*; **Maribel Santana,** *Project Coordinator.*

CARDIOVASCULAR SURGERY

The Department of Cardiovascular Surgery at The Mount Sinai Hospital is one of the most prestigious programs in the nation. The 2015–2016 *U.S. News & World Report* "Best Hospitals" issue ranked the cardiology and cardiovascular surgery institute, Mount Sinai Heart, as one of the top 10 in the country. Specialists at Mount Sinai are widely recognized for their excellence in cardiac care and their ability to blend research into clinical practice. Outstanding outcomes and an unwavering commitment to quality, safety, and patient satisfaction greatly benefit a large volume of national and international patients and their families every year. Cardiovascular surgery patients receive integrated and personalized care plans coordinated by world-renowned clinical cardiologists, experts in imaging and advanced diagnostic testing, cardiac anesthesiologists with expertise in perioperative transesophageal echocardiography, and specialized intensive care physicians. This multidisciplinary and comprehensive approach, in conjunction with continual enhancement of surgical technology and facilities, has led to a global reputation for cardiac surgical excellence. In addition, the Department of Cardiovascular Surgery at The Mount Sinai Hospital is an international hub for complex heart valve procedures and reoperations due to its surgical rigor and exhaustive risk assessment. ■



1. Specialists at Mount Sinai Heart are leaders in their fields, including David H. Adams, MD, a coauthor of the widest-selling valve textbook and a coinventor of the most commonly used mitral valve repair device in the world. Dr. Adams, left, is shown performing a procedure with Ahmed El-Eshmawi, MBChB.



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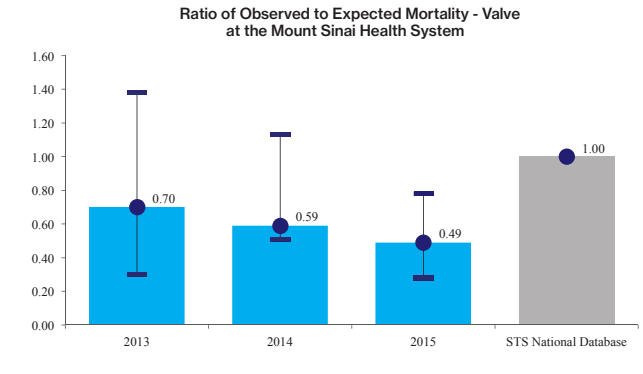

Source: Society of Thoracic Surgeons STS National Database

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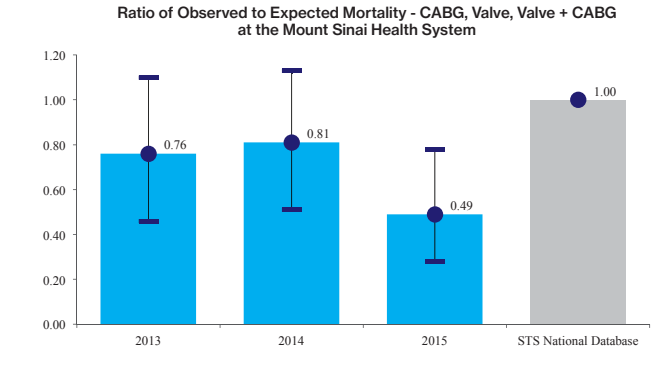

Source: Society of Thoracic Surgeons STS National Database

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2. The Mount Sinai Health System is one of the highest-volume cardiac surgery centers in the United States, with physicians experienced in a wide array of procedures, including coronary artery bypass grafting (CABG), valve, and valve plus CABG.

3. & 4. The rates of observed to expected mortality at the Mount Sinai Health System are significantly lower than the Society of Thoracic Surgeons benchmark for valve operations, CABG, and combined valve plus CABG operations.

MITRAL VALVE REPAIR

A Worldwide Center of Excellence in Mitral Valve Repair

David H. Adams, MD, *Cardiac Surgeon-in-Chief of the Mount Sinai Health System, Marie-Josée and Henry R. Kravis Professor and Chairman, Department of Cardiovascular Surgery, Icahn School of Medicine at Mount Sinai*

The overt operative and short-term clinical superiority of mitral valve repair over replacement with a prosthetic valve is well established and accepted by most cardiac specialists. Therefore, during the last decade, research and outcome analyses have focused on the long-term durability of mitral valve repair, particularly important in younger patients with degenerative mitral valve disease. In this context, the management of mitral valve regurgitation has changed drastically, and there has been a shift toward a more aggressive approach in terms of surgical timing and interpretation of the natural history of the disease. The latest literature has demonstrated the positive impact (better postoperative long-term survival) of early mitral valve repair, rather than waiting for symptoms such as ventricular dysfunction or dilatation, pulmonary hypertension, or atrial fibrillation—the standard guideline triggers for surgery in previous eras. However, the guidelines of the American College of Cardiology and the American Heart Association for the management of patients with valvular heart disease recommend early mitral valve repair only if the procedure is performed in a mitral valve reference center. The Mitral Valve Repair Reference Center at The Mount Sinai Hospital is among the world's best.

The Department of Cardiovascular Surgery at The Mount Sinai Hospital is chaired by David H. Adams, MD, a world-renowned expert in heart valve surgery and mitral valve reconstruction. Dr. Adams is the Director of the Mitral Valve Repair Reference Center at The Mount Sinai Hospital and leads a team of surgeons that performs more than 450 mitral valve procedures per year with superb outcomes. Among these, 62 percent are multivalve procedures. The volume of mitral valve repair procedures (and multivalve procedures including the mitral valve) at The Mount Sinai Hospital is the largest in New York State and among the highest in the world.

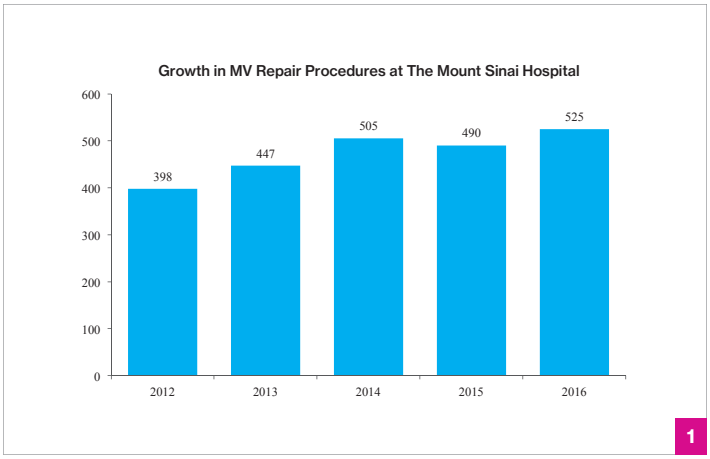
In terms of outcomes, Dr. Adams's team offers a greater than 99 percent repair rate for patients with degenerative mitral valve regurgitation and an 89 percent repair rate when including all the etiologies of mitral valve disease (degenerative disease, rheumatic disease, ischemic cardiomyopathy, acute endocarditis, mitral annular calcification, and congenital anomalies). The safety profile of the mitral team also sets national benchmarks, with an observed to expected mortality ratio of approximately 0.25 (compared with the Society of Thoracic Surgeons national average). Long-term freedom from regurgitation and reoperations after valve repair are among the highest ever reported by the leading mitral centers in the world.

Leading Innovations in Mitral Valve Disease

Dr. Adams and his team have been at the forefront of developing novel devices and approaches to facilitate mitral valve repair over the past decade. Dr. Adams is a coinventor with Alain Carpentier, MD, PhD,

About Dr. Adams

David H. Adams, MD, is the Marie-Josée and Henry R. Kravis Professor and Chairman of the Department of Cardiovascular Surgery at the Icahn School of Medicine at Mount Sinai and the Cardiac Surgeon-in-Chief of the Mount Sinai Health System. He is also President of the Mitral Foundation, a nonprofit organization dedicated to promoting best-practice standards in mitral valve disease. Dr. Adams is a recognized leader in the field of heart valve surgery. His surgical valve practice is one of the largest in the nation, and he has received the highest quality outcomes rating by the New York State Department of Health. He is a coauthor of the valve textbook *Carpentier's Reconstructive Valve Surgery* and is coeditor of the reference textbook *Cardiac Surgery in the Adult*. He is an inventor of many of the most widely used heart valve repair devices in current clinical practice and has given more than 350 invited lectures around the world. He is the current Vice President of the American Association for Thoracic Surgery.



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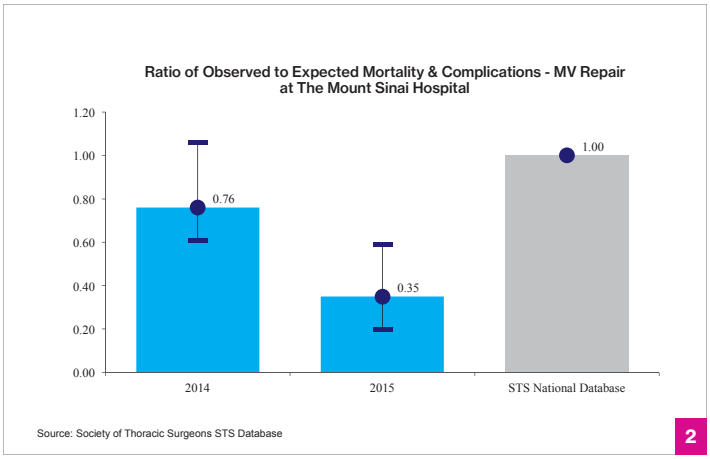

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MSH Mitral Valve Repair Reference Center Exceeds AHA/ACC Criteria for Early Intervention

	AHA/ACC	MSH
Mitral Valve Repair Procedures/Year	Not Specified	>450
Repair Rate	95%	>99%
Mortality Rate	<1%	<0.5%
Stroke Rate	<1%	<0.5%
Expert Periprocedural Imaging Capabilities	Yes	Yes
Heart Team with High-Risk Conference	Yes	Yes
Transparency Regarding Outcomes	Yes	Yes

3

of the Carpentier-Edwards Physio II Annuloplasty Ring (Edwards Lifesciences), which is the most widely used valve repair ring in the world. In addition, he is the inventor of the Tri-Ad™ Tricuspid Annuloplasty Ring (Medtronic), and coinventor of the Carpentier-McCarthy-Adams IMR ETlogix ring (Edwards Lifesciences). Furthermore, he and colleagues have developed novel minimally invasive retractor devices that facilitate limited-access incisions for mitral valve repair.

Mitral surgeons at The Mount Sinai Hospital are also leading clinical trials that may one day revolutionize less invasive mitral valve repair and replacement. Dr. Adams is the national co-principal investigator of the NeoChord FDA pivotal trial, which is establishing the efficacy of closed beating heart mitral valve repair through a mini-thoracotomy compared with open surgery. He and his team in November 2016 performed the first NeoChord repair procedure in the United States. This trial will expand to more than 20 centers in the nation and will be ongoing for the next few years.

In addition, Dr. Adams will serve as the national co-principal investigator of the Medtronic Intrepid FDA pivotal trial, which will establish the efficacy of transcatheter closed beating heart mitral valve replacement in patients with increased risk for conventional or surgical mitral valve replacement. This trial will begin in 2017 and is anticipated to involve more than 40 centers, including The Mount Sinai Hospital, during its course.

Mitral Foundation Leads the Way on Mitral Valve Disease

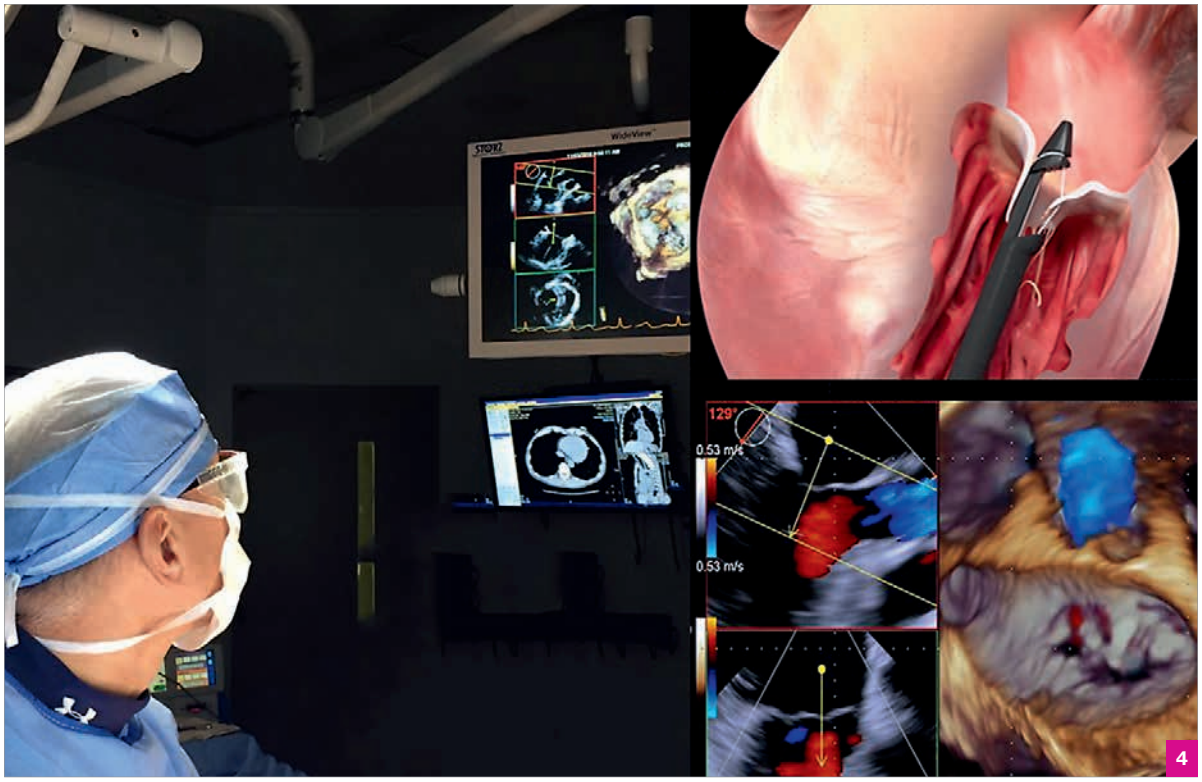
The Mitral Foundation is an important part of the Mount Sinai team's mission to be a leading resource for education in the treatment of mitral valve disease. The Mitral Foundation Center hosts several surgical education courses every year, in which surgeons come from all over the world to learn advanced techniques in valve reconstruction from Dr. Adams and his team. The Mitral Foundation is leading efforts to develop novel teaching tools for surgeons, including a collaboration with BioDigital Inc. to develop a virtual 3D heart for training purposes.

The Mitral Foundation also hosts the world's largest video teaching library of mitral valve repair procedures, with videos available to surgeons throughout the world. Finally, the Mitral Foundation leads educational missions to promote best practices in developing countries, including the Dominican Republic, Indonesia, Mexico, Thailand, and Vietnam. ■

1. The volume of mitral valve procedures at The Mount Sinai Hospital has risen steadily since 2012, with a projected total of 525 in 2016.

2. The observed to expected ratio of risk-adjusted mortality and morbidity at Mount Sinai indicates significantly better than expected performance.

3. The Mitral Valve Repair Reference Center exceeds all criteria for a Center of Excellence established by the American Heart Association/American College of Cardiology Guideline for Patients with Valvular Heart Disease.



4. In November 2016, David H. Adams, MD, performed the first NeoChord procedure in the United States, in a trial exploring the efficacy of beating-heart mitral valve repair, without the use of cardiopulmonary bypass, through a mini-thoracotomy.

5. A surgical education class at the Mitral Foundation, a Mount Sinai institution that hosts the world's largest video teaching library of mitral valve repair procedures, with videos available to surgeons around the globe.

Disclosure: The Icahn School of Medicine at Mount Sinai receives royalties related to Dr. Adams's intellectual property related to commercialized valve repair products from Edwards Lifesciences and Medtronic (but not in patients treated at Mount Sinai).

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Mitral Team

From left: Anelechi Anyanwu, MD, *Vice Chair of the Department of Cardiovascular Surgery*; **Percy Boateng, MD; Amit A. Pawale, MD; David H. Adams, MD,** *Chair of the Department of Cardiovascular Surgery*; **Ahmed E. El-Eshmawi, MBChB; Javier G. Castillo, MD.**

CORONARY REVASCULARIZATION

The Cardiac Catheterization Laboratory

Samin K. Sharma, MD, *Director of Clinical and Interventional Cardiology; Anandi Lal Sharma Professor of Medicine in Cardiology, Icahn School of Medicine at Mount Sinai, and* **Annapoorna S. Kini, MD,** *Director of the Cardiac Catheterization Laboratory at The Mount Sinai Hospital, and Zena and Michael A. Wiener Professor of Medicine (Cardiology), Icahn School of Medicine at Mount Sinai*

The Cardiac Catheterization Laboratory at Mount Sinai Heart is among the highest-volume, safest interventional catheterization laboratories in the United States. Consisting of seven adult catheterization rooms (three equipped for endovascular procedures), the Laboratory was established as the Mount Sinai Health System's tertiary center for complex coronary, valvular, and vascular interventions. Two of the rooms, hybrid catheterization laboratories, are equipped to perform transcatheter aortic valve replacement (TAVR). All catheterization rooms are equipped with intravascular ultrasound and fractional flow reserve capabilities. The Laboratory has incorporated other imaging modalities, such as optical coherence tomography and near-infrared spectroscopy. In addition, the group has access to the hybrid operating room suite, shared with the cardiovascular and vascular surgery teams, to perform TAVR requiring complex vascular access.

Among the highest volume and safest interventional catheterization laboratories in the United States.

The lab is led by Samin K. Sharma, MD, who received the prestigious two-star rating for safety for percutaneous coronary interventions (PCI) from the New York State Department of Health in 2016, as did the interventionalists Annapoorna S. Kini, MD, and George Dangas, MD, PhD. The Catheterization Laboratory is among the nation's busiest, with 9 full-time attending physicians, including 6 senior attendings (who provide guidance and help to other faculty during complex cases), 15 full-time affiliate attendings, 4 part-time attendings, and 11 voluntary attendings. The Laboratory consistently reports a high level of patient satisfaction, according to the 2014 survey of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS).

One important aspect of patient satisfaction is making the in-hospital stay as short as possible. With this in mind, approximately 62 percent of elective interventional patients are safely discharged on the day of their procedures (for ambulatory PCI) following an established ambulatory discharge protocol. Others with more complex interventions, comorbid conditions, and higher acuity are admitted for observation overnight with planned discharge home the next day.

Trends in Volume and Procedures

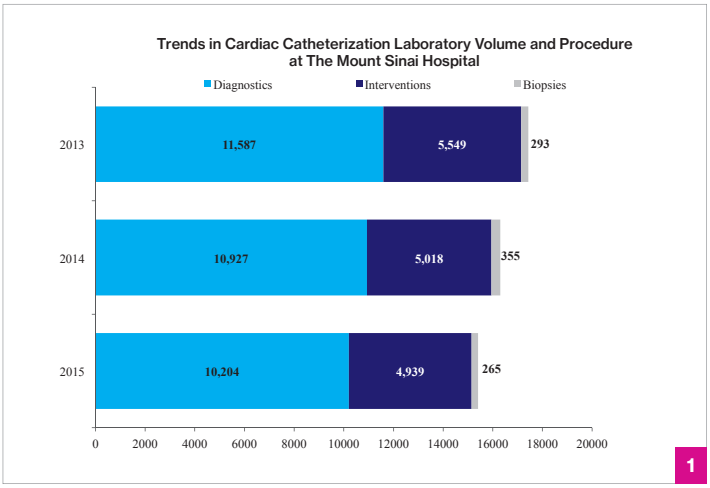
A high volume of diagnostic catheterization and interventional procedures is performed at The Mount Sinai Hospital Cardiac Catheterization Laboratory, with a low level of complications.

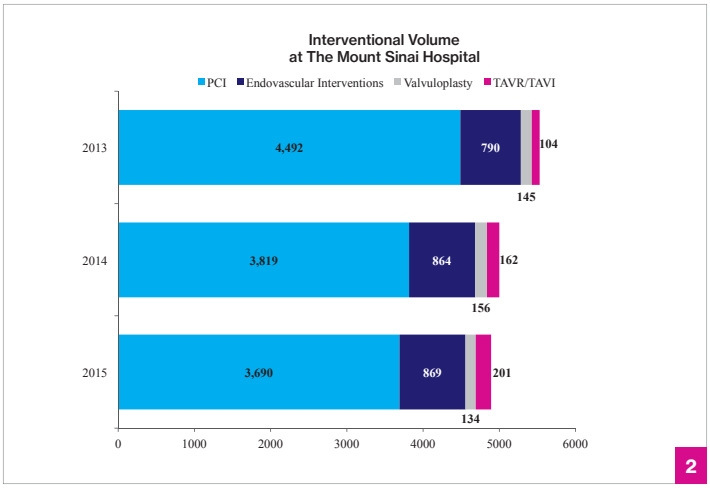
About Dr. Sharma

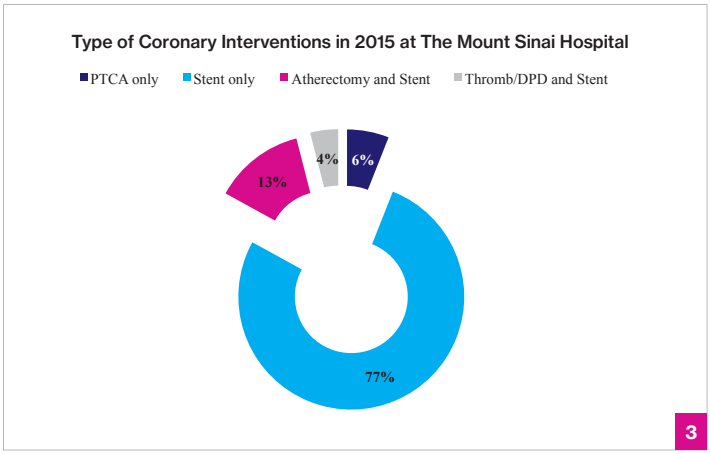
Samin K. Sharma, MD, FACC, is the Anandi Lal Sharma Professor of Medicine in Cardiology at the Icahn School of Medicine at Mount Sinai and leads the Cardiac Catheterization Laboratory at The Mount Sinai Hospital. Dr. Sharma, an international leader in his field, is known for performing one of the highest volumes of complex coronary interventions in the nation, with an extremely low complication rate. Dr. Sharma has served since 2004 on the Cardiac Advisory Board of New York State, which advises the Health Department and the Governor.

About Dr. Kini

Annapoorna S. Kini, MD, MRCP, FACC, is the Director of the Cardiac Catheterization Laboratory at The Mount Sinai Hospital, and is responsible for day-to-day smooth functioning of a very high-volume lab, which performs more than 15,000 total procedures, including 5,200 interventions, each year. Dr. Kini also serves as the Director of the Interventional Cardiology Fellowship Program, involving six to seven fellows from the United States and overseas. She specializes in the noncoronary interventions of mitral and aortic balloon valvuloplasty and alcohol septal ablation for obstructive hypertrophic cardiomyopathy.







New York State Department of Health 30-Day RAMR for PCI at The Mount Sinai Hospital

Years/Number of Cases		All Cases RAMR %	Non-Emergency Cases RAMR %	Interventionalist
2011–2013	3,925	0.56**	0.38**	Dr. Sharma
	2,883	0.60	0.31**	Dr. Kini
	439	0.18**	0.46	Dr. Dangas
2010–2012	4,052	0.51**	0.35**	Dr. Sharma
	2,874	0.29**	0.21**	Dr. Kini
2009–2011	3,063	0.47**	0.33	Dr. Kini
2008–2010	1,447	0.29**	0.24	Dr. Moreno
2006–2008	3,790	0.44**	0.32**	Dr. Sharma

Source: New York State Percutaneous Coronary Interventions Reporting System

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Total percutaneous interventions encompass these procedures: PCI for coronary artery disease; endovascular interventions (for diseased limb, cerebral, or renal arteries); valvuloplasties (for stenosed aortic or mitral valves); transcatheter aortic valve replacement/implantation for stenosed aortic valves; and alcohol septal ablation for hypertrophic obstructive cardiomyopathy. The majority of PCIs (94 percent) were done using stents—drug-eluting stents in 96 percent of these cases and bare metal stents in 4 percent. Among the coronary interventions, 77 percent were stent only, with 13 percent also including rotational or orbital atherectomy, 4 percent involving a thrombectomy/embolic-protection device, and the remaining 6 percent percutaneous transluminal coronary angioplasty (PTCA).

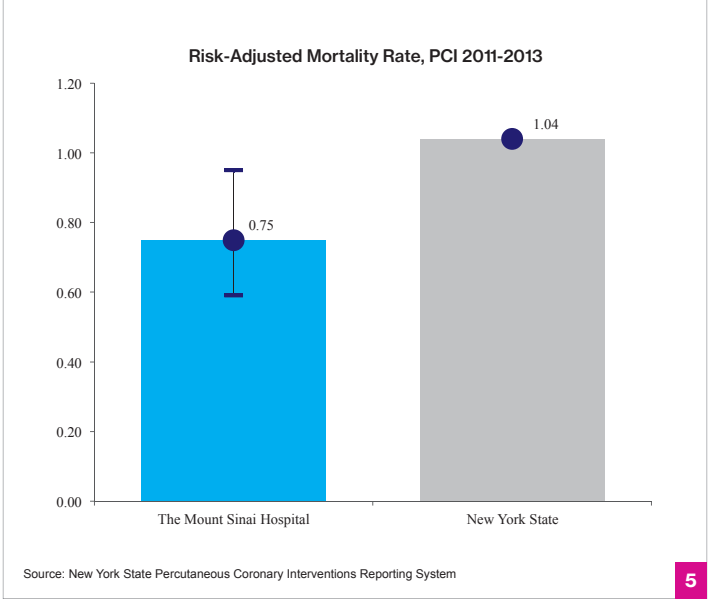
Strong Interventional Outcomes and Low Complication Rates

The system of established standard protocols, rigorous attention to minute detail, and a strong sense of teamwork have helped the Cardiac Catheterization

1. The volume of diagnostics, interventions, and biopsies at The Mount Sinai Hospital's Cardiac Catheterization Laboratory has been consistently high.

2. The Cardiac Catheterization Laboratory is a high-volume facility across a variety of interventional procedures.

3. Among coronary interventions, 77 percent were stent only, and an additional 13 percent also included rotational or orbital atherectomy.



Source: New York State Percutaneous Coronary Interventions Reporting System

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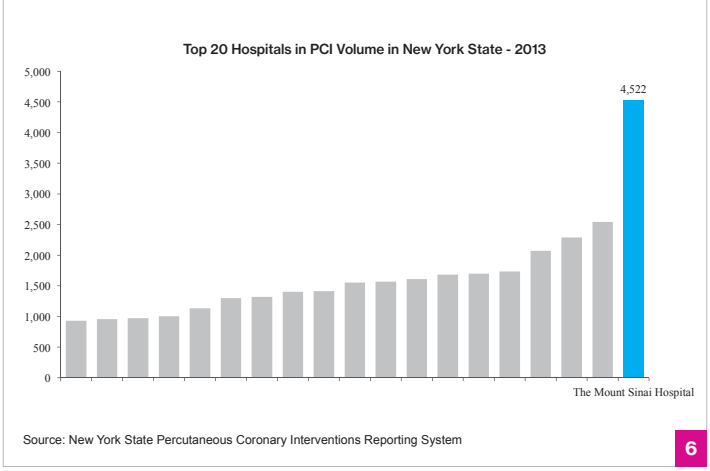

Source: New York State Percutaneous Coronary Interventions Reporting System

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Laboratory achieve some of the best interventional outcomes in the country. Its outcomes continue to improve every year, with unprecedented low procedural complications in 2015: the combined major complication of death, large MI, urgent CABG, and CVA cases was approximately 0.54 percent. This remarkably low complication rate was achieved despite high complexity and the comorbid medical conditions of the patients treated in the Catheterization Laboratory.

Reports of risk-adjusted PCI mortality over the last 17 years by the New York State Department of Health have consistently placed the Mount Sinai Catheterization Lab among the lowest for in-hospital and 30-day risk-adjusted mortality. The most recent state report of 30-day risk-adjusted mortality rates (RAMR), for 2013, showed the lab's incidence of 0.75 percent for all cases, 0.49 percent for elective cases, and 2.17 percent for emergency PCI cases to be about 30 percent lower than the statewide averages. According to the latest PCI report, for 2011–2013, the Laboratory was one of three centers to receive a double-star notation for superior safety in at least two PCI categories (all cases and nonemergency cases), denoting that a significantly lower RAMR than the statewide average was a constant.

This lower 30-day risk-adjusted mortality rate can be attributed in large part to the experience and high procedural volume of the five senior full-time interventionalists, who together perform more than 3,500 cases per year. The Laboratory's interventionalists frequently receive the prestigious two-star rating for PCI safety among the 600 practicing in the state.

Appropriate Care for Stable Coronary Artery Disease Patients

The appropriateness of PCI has recently come under strong scrutiny. Cases that are inappropriate based on the published guidelines are not only risky to the patient, since the intervention is not indicated, but also risk being denied reimbursement by the federal agencies. At Mount Sinai Heart, we implement an evidence-based protocol of evaluation for patients with coronary artery disease (CAD) before scheduling catheterization and possible intervention, and rigorously apply the appropriate-use criteria of the American College of Cardiology. This protocol has yielded one of the lowest rates of inappropriate PCI for stable CAD in the nation.

Low Mortality Rate for In-Hospital STEMI Patients

The rate of PCI procedures performed in fewer than 90 minutes is an important quality parameter of the Centers for Medicare & Medicaid Services and is publicly reported for all hospitals. The proportion of ST-elevation myocardial infarction (STEMI) patients at The Mount Sinai Hospital undergoing PCI in fewer than 90 minutes was 88 percent in 2015.

According to the 2015 American College of Cardiology–National Cardiovascular Data Registry report, the risk-adjusted mortality of STEMI patients at Mount Sinai Heart is approximately 50 percent lower than that of other comparable U.S. hospitals. ■

4. Three interventionalists at The Mount Sinai Hospital were awarded the prestigious two-star safety rating from the New York State Department of Health for percutaneous coronary intervention in 2011–2013, the most recent period reported.

5. The risk-adjusted mortality rate (RAMR) for percutaneous coronary intervention at The Mount Sinai Hospital was significantly lower than the New York State average in the most recent report released by the Department of Health.

6. The Cardiac Catheterization Laboratory at The Mount Sinai Hospital performed the largest number of PCI cases in New York State in 2013, the most recent data available.

Researchers Find Cholesterol Efflux Linked to Plaque Stabilization in Statin-Treated Patients

Researchers at the Mount Sinai Cardiac Catheterization Laboratory have found that patients treated with intensive statin therapy undergo changes in plaque morphology, specifically a thickening of the fibrous cap, that are associated with improved cholesterol transport and distinct genomic changes. The results of this study, YELLOW II (Reduction in Yellow Plaque by Aggressive Lipid-Lowering Therapy), were published October 29, 2016, in the *Journal of the American College of Cardiology*.

YELLOW II, led by Annapoorna S. Kini, MD, Director of the Cardiac Catheterization Laboratory and Professor of Medicine (Cardiology) at the Icahn School of Medicine at Mount Sinai, examined the mechanistic basis of changes in plaque morphology with a specific focus on how fat is removed from plaque. The study included 85 patients who underwent imaging of an obstructive nonculprit lesion with optical coherence tomography (OCT), near-infrared spectroscopy (NIRS), and intravascular ultrasound. Cholesterol efflux capacity (CEC) and gene expression were assessed. After enrollment, patients were treated with high doses of rosuvastatin (40 mg) for 8 to 12 weeks, and then CEC and genomic changes were reassessed with follow-up imaging. The promising results of YELLOW II offer a wider snapshot of how high-dose statin therapy exerts its influence, and point to underlying changes in gene expression that result from treatment, and may help to identify patients who respond to statin therapy without the need for invasive imaging.

A wider snapshot of how high-dose statin therapy exerts its influence.

YELLOW I, a study also led by Dr. Kini, was the first of its kind to use NIRS to demonstrate that short-term, high-dose statin treatment led to lipid regression in severely diseased arteries. Of the 87 patients enrolled in the first trial, half were treated with 40 mg doses of rosuvastatin, and the other half received standard lipid therapy. After seven weeks, the aggressive statin therapy led to lipid reduction in patients' severely obstructive coronary lesions, as measured by NIRS. As a result, the patients' fractional flow reserves improved, and they did not need stenting.

Also in the Cardiac Catheterization Laboratory, a series of bifurcation blockage cases inspired the Optical Coherence Tomography Bifurcation clinical trial, known as ORBID, which used OCT to identify the predictors of side branch occlusion after main branch stenting. The novel finding from ORBID is that lipid plaque in the main vessel may affect side branch occlusion after stenting. ORBID was the first study of its kind to demonstrate the association between lipid plaque and side branch occlusion, utilizing the unique imaging capability of OCT. ■

Next Frontier in Stent Technology: The Bioresorbable Vascular Scaffold

Mount Sinai Hospital interventional cardiologists were among the first in the United States to implant a fully dissolvable stent in patients with coronary artery disease. Approved by the U.S. Food and Drug Administration (FDA) in July, the Absorb GT1™ Bioresorbable Vascular Scaffold (BVS) system repairs and restores an artery to its naturally flexible and resilient form and then disappears.

Made from the naturally dissolving material polylactide, the Absorb stent is designed to address the problems of vessel restriction and restenosis that are associated with drug-eluting metal stents. The revolutionary stent is inserted into a diseased artery during PCI, where it releases the drug everolimus to prevent clot formation and gradually dissolves over about three years.

Samin K. Sharma, MD, Director of Clinical and Interventional Cardiology at The Mount Sinai Hospital and a Professor of Medicine (Cardiology) at the Icahn School of Medicine at Mount Sinai, was an investigator of the nationwide Absorb III clinical trial, in which the Absorb stent had comparable rates of major adverse cardiac events to the best-in-class drug-eluting stent XIENCE (7.8 percent for Absorb vs. 6.1 percent), with a slightly higher rate of scaffold thrombosis (1.54 percent for Absorb vs. 0.74 percent). Annapoorna S. Kini, MD, Director of the Cardiac Catheterization Laboratory and Professor of Medicine (Cardiology), Icahn School of Medicine at Mount Sinai, also served as a lead investigator in the trial.

Since its FDA approval, the Absorb stent has been placed in nearly 60 Mount Sinai patients with excellent results. Newer iterations of the Absorb stent, now in its first generation, will broaden its utility to a wider patient population. Second- and third-generation Absorb stents, which are thinner and more flexible, are in clinical trials in Europe and India. ■

Disclosure: Dr. Sharma receives financial compensation as a lecturer for Abbott Laboratories, the manufacturer of the Absorb GT1™ BVS.

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Sharma S, Baber U. The shifting pendulum for DAPT after PCI: balancing long-term risks for bleeding and thrombosis. J Am Coll Cardiol 2015;66(9):1046–9.

Team

Center, foreground: Samin K. Sharma, MD, FACC, *Director, Clinical and Interventional Cardiology*. **From left: Prakash Krishnan, MD, FACC,** *Director of Endovascular Services*; **Nitin Barman, MD; Annapoorna S. Kini, MD, MRCP, FACC,** *Director, Cardiac Catheterization Laboratory*; **Vishal Kapur, MD; Jason Kovacic, MD, PhD; Joseph M. Sweeny, MD, FACC; Roxana Mehran, MD; Usman Baber, MD, MS; Sameet Palkhiwala, MD;** and **George Dangas, MD, PhD, FACC.**

A Record of Safety and Innovation In Complex CABG Surgery

John D. Puskas, MD, *Chair of Cardiovascular Surgery at Mount Sinai St. Luke's and Mount Sinai Beth Israel, and Professor of Cardiovascular Surgery, Icahn School of Medicine at Mount Sinai*

The coronary bypass team, led by John D. Puskas, MD, focuses intensely on two things: safety and service. The Society of Thoracic Surgeons confirms that the mortality rate at Mount Sinai Beth Israel for isolated CABG was zero from January 1, 2015, through June 30, 2016. This means that the team performed more than 300 consecutive CABG cases without a single 30-day mortality. Moreover, there were no re-explorations for bleeding in that group of patients. Results for CABG, valve, and combined valve/CABG cases were similarly excellent: the observed to expected ratio for mortality has been less than 0.5 overall since January 1, 2015. This means that fewer than half as many patients have died after surgery at Beth Israel than would have been expected nationwide. Importantly, observed to expected ratios for major complications, prolonged ventilation, and re-exploration were all very low, some approaching zero.

Robotic-assisted CABG surgery is a natural extension of Dr. Puskas's efforts to reduce stroke, promote minimally invasive surgery, and prolong patient benefits with CABG. In this novel surgical approach, a sophisticated "robot" transmits the movements of Dr. Puskas's hands to long, thin instruments inserted between the patient's ribs into the chest, without opening the breastbone. This allows Dr. Puskas to harvest the internal thoracic artery, which is the preferred bypass graft conduit, from inside the chest wall and then suture it to the most important artery of the patient's heart—all without opening the chest, stopping the heart, or manipulating the aorta. Dr. Puskas has performed more than 200 such cases, without a stroke or mortality. Patients are discharged home in about three days, and many return to work within two weeks.

Always seeking to advance the field of coronary revascularization, Dr. Puskas has been a leader in adapting the robotic CABG procedure to patients who require more than a single bypass. By partnering with colleagues in interventional cardiology, he has popularized hybrid coronary revascularization, in which minimally invasive robotic bypass grafting is performed on the most important coronary artery and stenting is performed on one or more of the other coronary arteries. In carefully selected patients, this method may combine the durability of surgical grafting with the reduced invasiveness of stenting. Dr. Puskas was the national principal investigator of the Hybrid Observational Trial, sponsored by the National Institutes of Health and published in the *Journal of the American College of Cardiology* in 2016. He was recently awarded another NIH grant, along with colleagues in the Mount Sinai Department of Health Evidence and Policy, to lead a nationwide trial of hybrid revascularization among a network of 50 cardiac surgery centers throughout the United States.

Dr. Puskas and his operative team perform robotic CABG procedures at Mount Sinai Saint Luke's and The Mount Sinai Hospital in close partnership with leading cardiologists on both campuses. This heart team approach, in which cardiologists and cardiac surgeons collaborate to care for each coronary artery disease patient, enables Mount Sinai Heart to offer the very best innovations in cardiac care. ■

About Dr. Puskas

John D. Puskas, MD, FACC, FACS, is the Chair of Cardiovascular Surgery at Mount Sinai St. Luke's and Mount Sinai Beth Israel, and is a world-renowned adult cardiac surgeon with special expertise in coronary artery bypass grafting (CABG) surgery. Dr. Puskas has been a driving force in the adoption of multiple arterial grafts as an alternative to saphenous vein grafts in CABG surgery, and has led the development of advanced techniques for minimally invasive and off-pump CABG, in which the heart continues to beat throughout the operation. Dr. Puskas has delivered hundreds of lectures around the world, teaching innovative techniques that reduce the risk of stroke during CABG surgery (by minimizing aortic manipulation) and that prolong the benefit of revascularization (by utilizing all-arterial bypass grafts).

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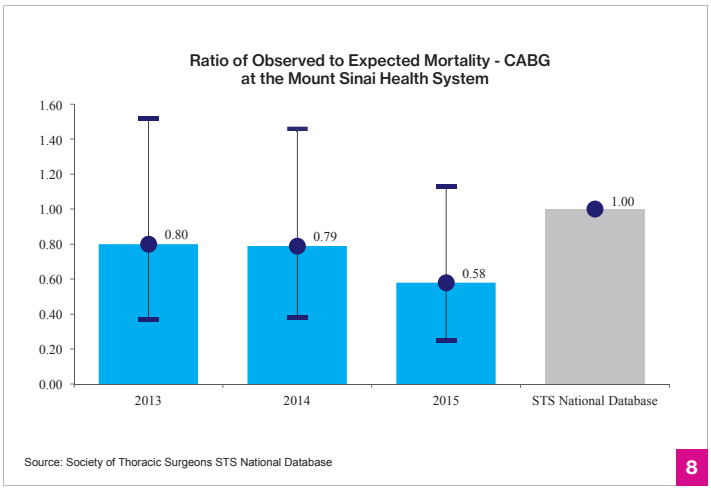

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Team

From left: Gianluca Torregrossa, MD; Gabriele Di Luozzo, MD, FACS; Sandhya K. Balaram, MD, PhD; Pedro R. Moreno, MD, FACC; John D. Puskas, MD, FACC, FACS, *Chair of Cardiovascular Surgery at Mount Sinai St. Luke's and Mount Sinai Beth Israel.*

7. In robotic assisted surgery, performed above by John D. Puskas, MD, long, thin instruments are inserted between the patient's ribs, without opening the chest or stopping the heart.

8. The quality indicator across the Health System showing observed to expected mortality in CABG procedures continues to indicate better than expected performance.

Endovascular Team Takes a Multidisciplinary Approach

Prakash Krishnan, MD, FACC, *Director of Endovascular Interventions at The Mount Sinai Hospital's Cardiac Catheterization Laboratory and Assistant Professor of Medicine (Cardiology), Icahn School of Medicine at Mount Sinai*

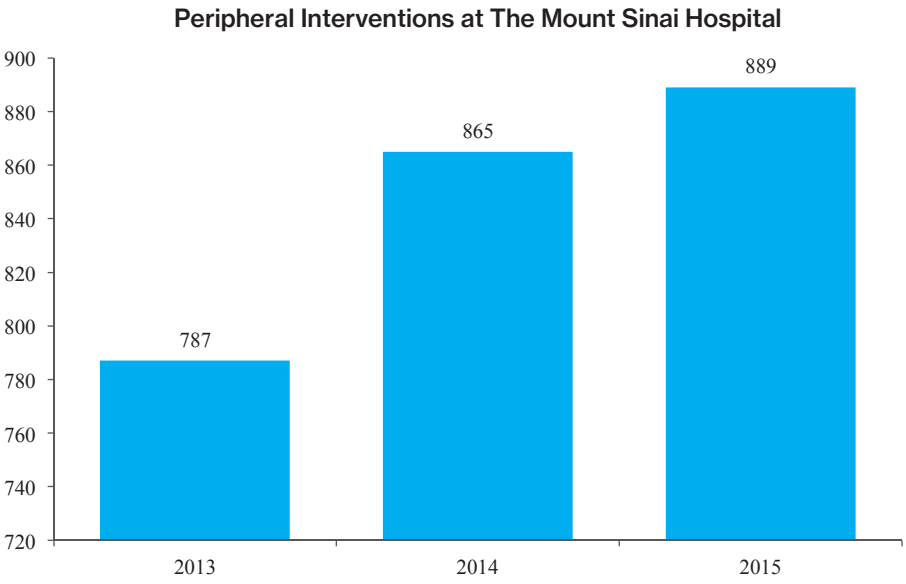
The Endovascular Interventions team, led by Prakash Krishnan, MD, FACC, provides high-quality treatment to diseased blood vessels outside the heart. The team's endovascular cardiologists take a multidisciplinary approach, working with other physicians trained in vascular medicine, vascular surgery, interventional radiology, radiology, neurology, and podiatry to create comprehensive treatment plans to care for the whole person. The team's three interventionalists perform a full range of vascular and endovascular procedures including:

- Endovascular repair to multiple vascular beds with balloon angioplasty, stenting, and atherectomy (directional, rotational, orbital, and laser)
- Endovascular repair of peripheral aneurysms, such as popliteal artery aneurysms and renal artery aneurysms
- Carotid artery stenting
- Endovenous laser therapy and radiofrequency ablation for varicose veins and ulcers
- Phlebectomy and sclerotherapy for varicose veins
- Endovascular treatment for deep venous occlusions
- Endovascular treatment for critical limb ischemia
- Treatment for vascular-associated conditions such as nutcracker syndrome, superior vena cava syndrome, and Paget-Schroetter syndrome.

Physicians and researchers on the team are actively involved in translational and clinical studies that provide new alternatives in the diagnosis and treatment of vascular diseases, leading or participating in large-scale national and international clinical trials. A particular area of interest is peripheral arterial disease (PAD), which affects nearly 200 million people worldwide. About one million people in the United States are living with limb loss due to PAD, and half of them will die within five years of the amputation. Dr. Krishnan is an international expert in limb-loss prevention, with patients traveling from all over the world to receive treatment. Drug-eluting balloon technology has been a game changer in the endovascular treatment of PAD. Paclitaxel coating technology has reduced restenosis, compared with traditional angioplasty. Dr. Krishnan is a leading enroller in drug-eluting balloon studies and the national principal investigator for the pivotal ILLUMENATE drug-eluting balloon study. ■

About Dr. Krishnan

Prakash Krishnan, MD, FACC, is the Director of Endovascular Interventions at The Mount Sinai Hospital's Cardiac Catheterization Laboratory and Assistant Professor of Medicine (Cardiology), Icahn School of Medicine at Mount Sinai. He is an international expert on drug-eluting balloon technology and was the first to deploy the Paclitaxel-eluting balloon in the United States. Dr. Krishnan, a leading educator and researcher, founded peripheralinterventions.org, an online resource for other interventional cardiologists and endovascular surgeons to watch and interact with Dr. Krishnan during complex cases. He is also the Director of the endovascular component of the international Complex Coronary, Valvular and Vascular Cases Symposium. His other areas of research expertise include the molecular mechanism of atherosclerotic restenosis, vascular imaging, and the creation of a distal embolic protection algorithm.



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Selected Publications

Krishnan P, Purushothaman KR, Purushothaman M, Baber U, Tarricone A, Vasquez M, Wiley J, Kini A, Sharma SK, O'Connor WN, Moreno PR. Relation of internal elastic lamellar layer disruption to neointimal cellular proliferation and type III collagen deposition in human peripheral artery restenosis. Am J Cardiol 2016;117(7):1173–9.

Krishnan P, Purushothaman KR, Purushothaman M, Turnbull IC, Tarricone A, Vasquez M, Jain S, Baber U, Lascano RA, Kini AS, Sharma SK, Moreno PR. Enhanced neointimal fibroblast, myofibroblast content and altered extracellular matrix composition: implications in the progression of human peripheral artery restenosis. Atherosclerosis 2016;251:226–33.

Krishnan P, Tarricone A, Ali Z, Purushothaman KR, Overbey J, Vasquez M, Wiley J, Kapur V, Gujja K, Atallah RT, Nasiadko K, Kini A, Sharma S. Intravascular ultrasound is an effective tool for predicting histopathology-confirmed evidence of adventitial injury following directional atherectomy for the treatment of peripheral artery disease. J Endovasc Ther 2016;23(4):672–3.

9. Interventions for peripheral arterial disease rose in each of the last three years at The Mount Sinai Hospital, an international leader in treating the disorder.

Cardiac Catheterization in Pediatric and Adult Congenital Heart Disease

Barry A. Love, MD, FSCAI, *Director of the Congenital Cardiac Catheterization Laboratory at The Mount Sinai Hospital, and Assistant Professor of Medicine (Cardiology) and Pediatrics, Icahn School of Medicine at Mount Sinai*

The Congenital Cardiac Catheterization Laboratory at The Mount Sinai Hospital is one of the leading centers for diagnostic and interventional procedures in the nation. Headed by Barry A. Love, MD, FSCAI, it is one of the few centers that can treat the full spectrum of congenital heart disease from infancy through adulthood.

The Catheterization Laboratory recently underwent a full renovation and upgrade to new Philips biplane imaging equipment, especially focused on reducing radiation exposure. The new equipment, combined with other dose-reducing techniques, has decreased X-ray exposure by at least 50 percent in most cases, without compromising image quality. This is a major quality improvement for patients and for the Laboratory staff. Increasing use of three-dimensional echocardiography has also improved image guidance while minimizing the harmful effects of ionizing radiation.

Ductal stenting for patients with single-ventricle physiology, as an alternative to the surgical Blalock-Taussig shunt, is one of Mount Sinai's advances in the treatment of infants with heart disease. Dr. Love is one of the few operators who is able to offer this approach for infants as part of staged congenital heart disease management. Delivering a coronary stent by catheterization, instead of a major operation to place a shunt from the subclavian artery to the pulmonary artery, allows for more reliable pulmonary blood flow and much faster recovery. A ductal stent also simplifies subsequent surgery. Translating the experience of Samin K. Sharma, MD, and his coronary team to the pediatric context has allowed Dr. Love unprecedented ability to use these tiny stents to benefit the smallest patients.

Many adolescents and adults with repaired Tetralogy of Fallot, those with truncus arteriosus, and patients who have undergone a Ross procedure will require pulmonary valve replacement to preserve right heart function. Transcatheter pulmonary valve replacement was first performed at Mount Sinai in 2010 using the first-generation Medtronic Melody® valve. This was a groundbreaking advance in treating children and adults with congenital heart disease, but the maximum diameter of 22 mm limited the use of the valve to patients with smaller pulmonary diameters. In 2016, the FDA approved the Edwards SAPIEN XT valve, which has a maximal expanded diameter of 29 mm, for use in the pulmonary position. This has allowed the team to extend transcatheter valve replacement in the pulmonary position to many more patients. Dr. Love has partnered with Jason C. Kovacic, MD, PhD, who has been instrumental in developing the transcatheter aortic valve program at Mount Sinai, to offer the Edwards valve to a larger group of patients. In March 2016, this physician team implanted the first FDA-approved SAPIEN XT valve in the United States in a 22-year-old man with a history of repaired Tetralogy of Fallot, avoiding another major operation.

For both pediatric and adult patients, transcatheter closure of atrial septal defects (ASDs) has been one of the major advances in congenital heart catheterization. In 2016, a new occluder (the GORE® CARDIOFORM) was approved, offering a lower profile and better closure for many ASDs. Mount Sinai will be one of 20 U.S. centers participating in a trial starting in the first quarter of 2017 of an exciting new generation of ASD occluders that will extend the size of ASDs that can be closed.

These are just some of the ways the Congenital Cardiac Catheterization Laboratory continues to be a leader in the field, drawing on the unique strengths of Mount Sinai's heart team. ■

About Dr. Love

Barry A. Love, MD, FSCAI, is the Director of the Congenital Cardiac Catheterization Laboratory at The Mount Sinai Hospital. Dr. Love, who holds a joint appointment in the Department of Pediatrics and the Department of Medicine, is one of only a few physicians who perform interventional procedures on patients with congenital heart disease from infancy through adulthood. Dr. Love has authored numerous papers and book chapters on congenital heart disease as well as interventional catheterization in congenital and structural heart disease. He is a principal investigator for several new device trials, and he is a pioneer in extending many of the techniques used in the treatment of congenital heart disease to adults' acquired heart lesions, such as perivalvular leaks and postinfarction ventricular septal defects.

VASCULAR DISEASE

Four Groups Closely Collaborate For a Patient-Focused Team Approach

Jeffrey W. Olin, DO, *Director of Vascular Medicine, Mount Sinai Heart and Professor of Medicine (Cardiology) at the Icahn School of Medicine at Mount Sinai*

Mount Sinai enjoys a unique collaboration among four vascular groups: Vascular Medicine, Vascular Surgery, Interventional Radiology, and Interventional Cardiology. The collaboration occurs on all levels—patient care, conferences on care, outcomes and complications, cross training of fellows, and research—and it leads to the excellent care and outcomes for which Mount Sinai Heart is known.

Vascular Medicine

Mount Sinai is one of the few institutions with a section on Vascular Medicine within its cardiovascular department. In addition to treating both common and unusual noncardiac vascular disease, Mount Sinai's Vascular Medicine section is notable for its high-volume and high-quality vascular laboratory and for treating patients with fibromuscular dysplasia from all over the world. The vascular diagnostic laboratory is fully accredited by the Intersocietal Accreditation Commission in four areas: peripheral arterial, venous, physiologic testing, and visceral vascular. All of its technologists are certified vascular technologists, and all of its interpreting physicians have either the registered vascular technologist (RVT) or registered physician in vascular interpretation (RPVI) certification, indicating the section's commitment to excellence.

A Leader in Treating Fibromuscular Dysplasia

Fibromuscular dysplasia (FMD) is an arterial condition that primarily affects women between the ages of 20 and 60. It is characterized by an abnormal growth of cells in the artery, and it can be a cause of high blood pressure, stroke, and heart attack in women who do not have the usual cardiovascular risk factors.

Patients from all over the world come to Mount Sinai's Vascular Medicine section for care of this under-recognized and poorly treated condition. The research at Mount Sinai has changed the fundamental understanding of this disease, and study in the genetics of FMD (with the expertise of Jason Kovacic, MD, PhD) has been making steady progress. Dr. Olin leads the United State Registry for Fibromuscular Dysplasia, which has more than 1,400 patients enrolled. From 2010 to 2016, there were 1,171 patient visits to our Fibromuscular Dysplasia Care and Research team.

Working closely with colleagues in Interventional Radiology, the team performed 143 procedures from 2011 to 2015 involving the kidneys and the cerebrovascular and extremity arteries. ■

About Dr. Olin

Jeffrey W. Olin, DO, is the Director of the Vascular Medicine section within Mount Sinai Heart and Professor of Medicine (Cardiology) at the Icahn School of Medicine at Mount Sinai. Dr. Olin, an international leader in vascular ultrasound, has developed new noninvasive techniques to evaluate patients for renal artery stenosis and treat catheter-associated pseudoaneurysms. Dr. Olin has been involved in clinical research involving venous thromboembolic disease, fibromuscular dysplasia, peripheral artery disease, renal artery disease, and carotid artery disease. He was instrumental in the formation of the American Board of Vascular Medicine and is a past president of the Society for Vascular Medicine, a Fellow of the American College of Cardiology, and a Fellow of the American Heart Association.

Distribution of Studies Performed in 2015

Diagnostic Test	Total (Year 2015)
Aortoiliac Ultrasound	273
Carotid Duplex Ultrasound	2,062
Hemodialysis Access Ultrasound	244
Lower Extremity Pulse Volume Recordings and Ankle-Brachial Index	1,660
Lower Extremity Arterial Duplex Ultrasound	1,246
Lower Extremity Venous Duplex Ultrasound	2,396
Mesenteric Duplex Ultrasound	34
Renal Artery Duplex Ultrasound	621
Ultrasound Guided Thrombin Injection	60
Upper Extremity Pulse Volume Recordings and Ankle-Brachial Index	68
Upper Extremity Arterial Duplex Ultrasound	142
Upper Extremity Venous Duplex Ultrasound	375
Vena Cava and Iliac Veins Ultrasound	110

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Selected Publications

Kadian-Dodov D, Gornik HL, Gu X, Froehlich J, Bacharach JM, Chi YW, Gray BH, Jaff MR, Kim ESH, Mace P, Sharma A, Kline-Rogers E, White C, Olin JW. Dissection and aneurysm in patients with fibromuscular dysplasia: findings from the United States Registry for FMD. J Am Coll Cardiol 2016;68:176-85.

Kiando SR, Tucker NR, Castro-Vega LJ, Katz A, d'Escamard V, Tréard C, Fraher D, Albuisson J, Kadian-Dodov D, Ye Z, Austin E, Yang ML, Hunker K, Barlassina C, Cusi D, Galan P, Empana JP, Jouven X, Gimenez-Roqueplo AP, Bruneval P, Hyun Kim ES, Olin JW, Gornik HL, Azizi M, Plouin PF, Ellinor PT, Kullo IJ, Milan DJ, Ganesh SK, Boutouyrie P, Kovacic JC, Jeunemaitre X, Bouatia-Naji N. PHACTR1 is a genetic susceptibility locus for fibromuscular dysplasia supporting its complex genetic pattern of inheritance. PLoS Genetics 2016;12(10):e1006367.

Michelis KC, Olin JW, Kadian-Dodov D, d'Escamard V, Kovacic JC. Coronary artery manifestations of fibromuscular dysplasia. J Am Coll Cardiol 2014;64:1033-46.

Olin JW, Gornik HL, Bacharach JM, Biller J, Fine LJ, Gray BH, Gray WA, Gupta R, Katzen BT, Lookstein RA, Lumsden AB, Newburger JW, Rundek T, Sperrati JC, Stanley JC. Fibromuscular dysplasia: state of the science and critical unanswered questions. Circulation 2014;129:1048-78.

1. A wide spectrum of diagnostic tests was performed in 2015 by Mount Sinai's Vascular Medicine section.

2. Fibromuscular dysplasia, as seen via a catheter-based angiogram.

A Guiding Force in Cardiovascular Research And Clinical Care

Jonathan L. Halperin, MD, *Robert and Harriet Heilbrunn Professor of Medicine at the Icahn School of Medicine at Mount Sinai, and Associate Director of the Zena and Michael A. Wiener Cardiovascular Institute of the Mount Sinai Health System*

Jonathan L. Halperin, MD, joined the faculty at Mount Sinai in 1980 and played a key role in the formation of the Zena and Michael A. Wiener Cardiovascular Institute. Having introduced strategies for stroke prevention that are now in use by millions of patients worldwide, Dr. Halperin has shifted his attention to defining the optimum management of individual patients. His current work is addressing populations defined by advanced age; frailty; comorbidities like diabetes, hypertension, or heart failure; and concurrent conditions, including acute coronary syndromes, coronary stents, and prosthetic heart valves. On December 31, 2016, Dr. Halperin finished a decade of service on the American College of Cardiology (ACC)/American Heart Association Task Force on Practice Guidelines, the last few years as Chair, and he remains Co-Chair of the Clinical Competency Committee of the ACC. At The Mount Sinai Hospital, he is partnering with a team, including Information Technology, to develop software systems that deliver information on drugs, procedures, and devices to doctors in real time, at the point of care.

These efforts all focus on guiding physicians on how and when to employ treatments in the context of comprehensive patient management, and ensuring that doctors have the knowledge, skills, and direction to provide high-quality cardiac care. At the core is the need to prevent the cardiovascular pathology predisposing patients to risk, and this requires translating medical research discoveries into practical measures that patients and their families can understand and apply. These are the links among the molecular biochemistry of drug development, clinical trials that prove safety and effectiveness, and the implementation science that assures delivery on the promise.

Among Dr. Halperin's principal research activities, he has led clinical trials that have introduced strategies to prevent stroke among the millions of people with atrial fibrillation. He was the principal cardiologist responsible for the Stroke Prevention in Atrial Fibrillation (SPAF) clinical trials and was Co-Chair of the Executive Committee of the SPORTIF trials, which evaluated the first oral direct thrombin inhibitor, and he served on the leadership committee of the trial that evaluated the first oral factor Xa inhibitor for this indication. Dr. Halperin is currently developing therapeutic approaches to an array of cardiovascular disease states, including atrial fibrillation and venous thromboembolism. ■

About Dr. Halperin

Jonathan L. Halperin, MD, is the Robert and Harriet Heilbrunn Professor of Medicine at the Icahn School of Medicine at Mount Sinai, and the Associate Director of the Zena and Michael A. Wiener Cardiovascular Institute of the Mount Sinai Health System. His principal research activities have involved leading clinical trials that have introduced strategies to prevent stroke among the millions of people with atrial fibrillation. Dr. Halperin serves on consensus panels that issue clinical-practice guidelines for management of patients with various cardiovascular disorders, and he chaired the American College of Cardiology and American Heart Association Task Force on Practice Guidelines, which establishes standards of care in the United States. In the field of professional medical education, he is Co-Chair of the Clinical Competency Committee of the American College of Cardiology and Deputy Editor of the *Journal of the American College of Cardiology*.

Vascular Surgery

Michael L. Marin, MD, *Dr. Julius H. Jacobson II Professor and Chair of the Department of Surgery, Icahn School of Medicine at Mount Sinai,* and **Peter L. Faries, MD,** *Franz W. Sichel Professor of Surgery and Chief of the Division of Vascular and Endovascular Surgery*

The Division of Vascular and Endovascular Surgery at the Icahn School of Medicine at Mount Sinai offers the latest in minimally invasive catheter-based treatment for arterial disease, aneurysms, and venous disease. Over the past decade, dramatic advances in the treatment of patients with vascular disease have occurred. The surgical team at Mount Sinai has been at the forefront of these patient-care improvements, developing new techniques to minimize discomfort and improve outcomes. These advances include minimally invasive treatments for the prevention of stroke and for the repair of aortic aneurysms. Peter L. Faries, MD, Chief of the Division of Vascular and Endovascular Surgery, and Michael L. Marin, MD, Chair of the Department of Surgery, Icahn School of Medicine at Mount Sinai, have assembled a team of internationally recognized surgeons dedicated to clinical excellence and comprehensive patient care.

Many of the surgeons in the Vascular Surgery division are internationally renowned and attract patients from all over the world who are seeking the newest surgical approaches available. The physicians performed 15,742 vascular surgeries from 2008 to 2015. A total of 2,309 were performed in 2015, with mortality and complication rates that were significantly lower than expected.

Interventional Radiology

The Division of Interventional Radiology was one of the first in the nation to perform diagnostic angiography, percutaneous nephrostomy, nonsurgical treatment for uterine fibroids, and transarterial therapy for liver cancer. Mount Sinai was also one of the first sites to employ drug-eluting stents for the treatment of peripheral arterial disease to restore circulation to the legs. The Division is led by Robert A. Lookstein, MD, Professor of Radiology and Surgery at the Icahn School of Medicine at Mount Sinai and Vice Chairman in the Department of Radiology, who oversees all interventional services for the Mount Sinai Health System.

A range of procedures, including the latest minimally invasive treatments for aneurysms and arterial and venous diseases.

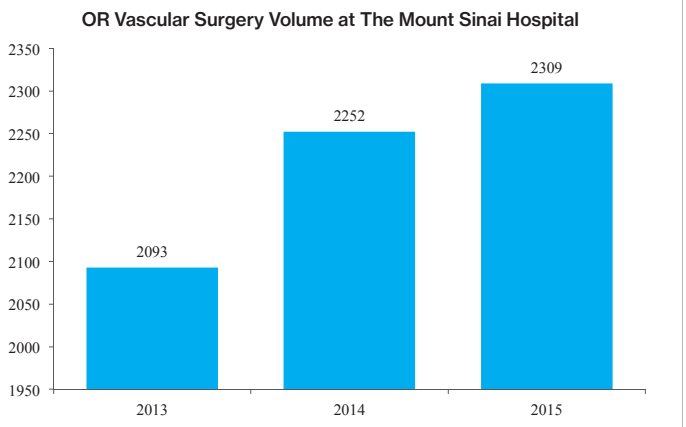
The five full-time faculty members in the Division perform more than 6,000 procedures each year, offering safe, minimally invasive treatment options for patients from throughout the region and nation as well as from Canada, South America, and Europe. The team's physicians collaborate in a multidisciplinary approach with experts in Cardiology, Cardiovascular Surgery, Transplantation, Obstetrics and Gynecology, and Women's Health, treating vascular disease, cancer, venous conditions, and liver and kidney disease. The team also works closely with Allan S. Stewart, MD, Director of Aortic Surgery, at the forefront of treating fibromuscular dysplasia. ■

About Dr. Marin

Michael L. Marin, MD, is the Dr. Julius H. Jacobson II Professor and Chair of the Department of Surgery, Icahn School of Medicine at Mount Sinai, and is a leader in modern vascular surgery. In 1992, he performed the first minimally invasive repair of an abdominal aortic aneurysm in the United States, sparking the rapid development of new treatments by Dr. Marin and by other physicians. Dr. Marin also performed the world's first endovascular repair of a ruptured abdominal aortic aneurysm. Inventions and techniques resulting from his work have formed the basis of 12 important U.S. patents.

About Dr. Faries

Peter L. Faries, MD, is the Franz W. Sichel Professor of Surgery and Chief of the Division of Vascular and Endovascular Surgery, and is an expert in the treatment of carotid artery disease for the prevention of stroke. He has helped advance the practice of minimally invasive vascular surgery, particularly the use of percutaneous techniques that can effectively improve arterial blood flow without the need for more invasive, traditional open surgery. Dr. Faries leads a laboratory that is studying the root causes of aortic aneurysm and whether stem cells can treat the condition.



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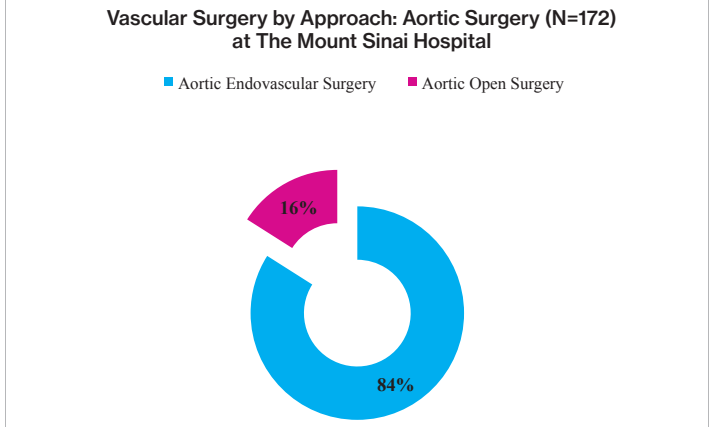

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Vascular Surgery 2015

Vascular Surgery	
Vascular Surgeries (Open and Endovascular)	2,309
Bypass Surgeries	150
Arteriovenous Access Surgeries	345
Vascular Interventional Radiology Procedures	368
Aortic Surgery	
Open Ascending Aorta and Aortic Arch Repairs	145
Open Descending Aorta and Thoracoabdominal Repairs	15
Open Abdominal Aortic Aneurysm Repairs	12
Endovascular Descending Aorta and Thoracoabdominal Repairs	35
Endovascular Abdominal Aortic Aneurysm Repairs	110
Carotid Surgery	
Carotid Endarterectomy	130
Carotid Stent	115
Percutaneous Revascularization Procedures	**1,100**

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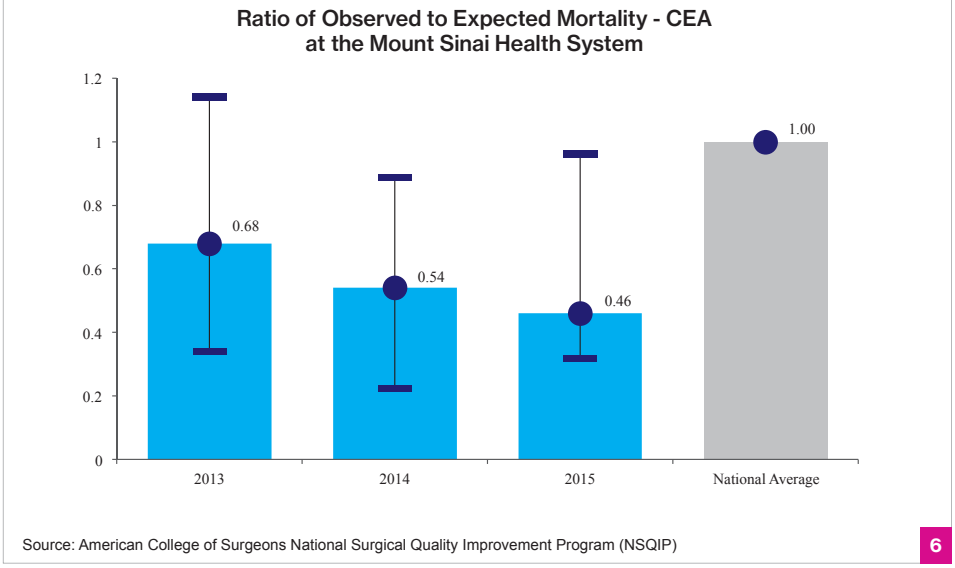

Source: American College of Surgeons National Surgical Quality Improvement Program (NSQIP)

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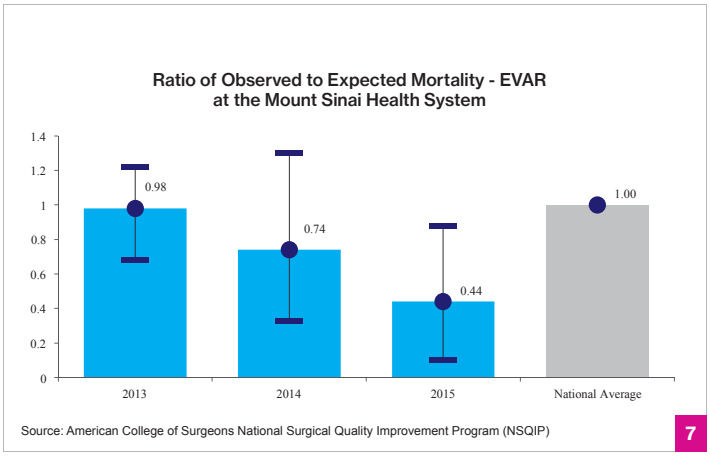
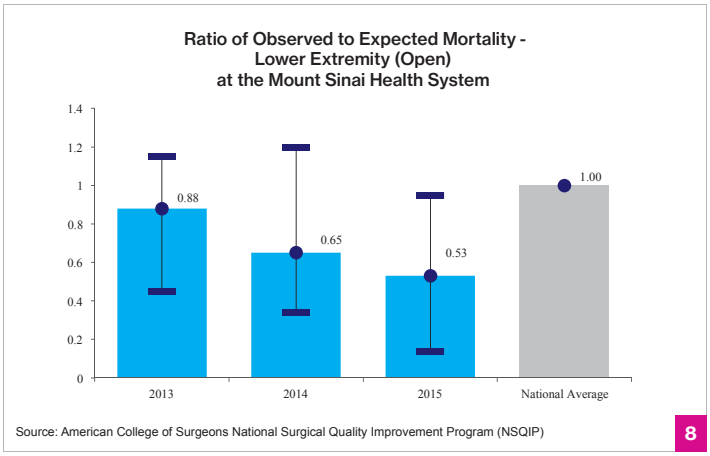
3. Operating room volume for vascular surgery has risen steadily at The Mount Sinai Hospital since 2013, to 2,309 procedures in 2015.

4. Aortic endovascular surgery, the less invasive and often preferred approach, made up 84 percent of vascular surgeries at The Mount Sinai Hospital.

5. The surgical team at The Mount Sinai Hospital performed a range of procedures in 2015 for arterial disease, aneurysms, and venous diseases.





Selected Publications

Beckerman WE, Tadros RO, Faries PL, Torres M, Wengerter SP, Vouyouka AG, Lookstein RA, Marin ML. No major difference in outcomes for endovascular aneurysm repair stent grafts placed outside of instructions for use. J Vasc Surg 2016;64(1):63–74.

Png CY, Tardiff M, Tadros RO, Faries PL, Kaplan D, Vouyouka AG, Marin ML, Stoner M. Vascular surgeon-hospitalist co-management improves in-hospital mortality at the expense of increased in-hospital cost. J Vasc Surg (In Press).

Ravin RA, Gottlieb A, Pasternac K, Cayne N, Schneider D, Krishnan P, Marin ML, Faries PL. Carotid artery stenting may be performed safely in patients with radiation therapy-associated carotid stenosis without increased restenosis or target lesion revascularization. J Vasc Surg 2015; 62:624–30.

Team

From left: Allan S. Stewart, MD, *Director of Aortic Surgery*; **Jeffrey W. Olin, DO,** *Director of Vascular Medicine*; **Paul Stelzer, MD; Peter L. Faries, MD,** *Chief of the Division of Vascular and Endovascular Surgery.*

6.–8. The ratio of observed to expected mortality at the Mount Sinai Health System was significantly lower than average for carotid endarterectomy, endovascular abdominal aneurysm repair, and lower extremity open surgery.

AORTIC VALVE AND AORTIC SURGERY




Deep Experience in Aortic Treatment, From Surveillance to Complex Surgery

Allan S. Stewart, MD, *Director of Aortic Surgery in the Department of Cardiovascular Surgery and Associate Professor of Cardiovascular Surgery,* and **Paul Stelzer, MD,** *Professor of Cardiovascular Surgery, Icahn School of Medicine at Mount Sinai*

Gabriele Di Luozzo, MD, *Associate Professor of Cardiovascular Surgery and Director of Aortic Surgery, Mount Sinai St. Luke's,* and **David H. Adams, MD,** *Cardiac Surgeon-in-Chief of the Mount Sinai Health System, Marie-Josée and Henry R. Kravis Professor and Chairman, Department of Cardiovascular Surgery, Icahn School of Medicine at Mount Sinai*

The Department of Cardiovascular Surgery at Mount Sinai has had a longstanding interest in the disease and surgery of the thoracic and thoracoabdominal aorta. Results of the first series of aortic arch operations were published in 1975 by the pioneering surgeon Randall B. Griepp, MD. The team at the Center for Aortic Disease, now under the direction of Drs. Stewart and Di Luozzo, continues this tradition of research and advanced care, focusing on all aspects and stages of aortic aneurysms. The outcomes of aortic surgery at Mount Sinai Heart have consistently been the benchmark for other programs worldwide.

The team begins its assessment of patients by enrolling them in the Mount Sinai Aortic Surveillance Program. Established in 1985, the Program is one of the largest of its kind in the nation. This stringent multidisciplinary program for patients with thoracic aortic aneurysms and dissections carefully monitors changes in the size of the aneurysm in order to provide the most effective, customized treatment. Patients from as far as Europe and Asia come to Mount Sinai to participate in the Program.

Mount Sinai is a leading referral center for thoracic aortic aneurysms in the United States, not only because of its clinical expertise and history, but because of its strength in basic and clinical research. Mount Sinai's confidential database of more than 4,000 participants helps identify risks, common complications, and aneurysm-growth expectations—all of which can lead to better patient care. If surgery is needed, the Program offers innovative care for both elective and emergency aortic procedures. The Program is also researching the genetic causes of serious aortic disease and minimally invasive methods of treating it.

A few facts about the Center for Aortic Disease:

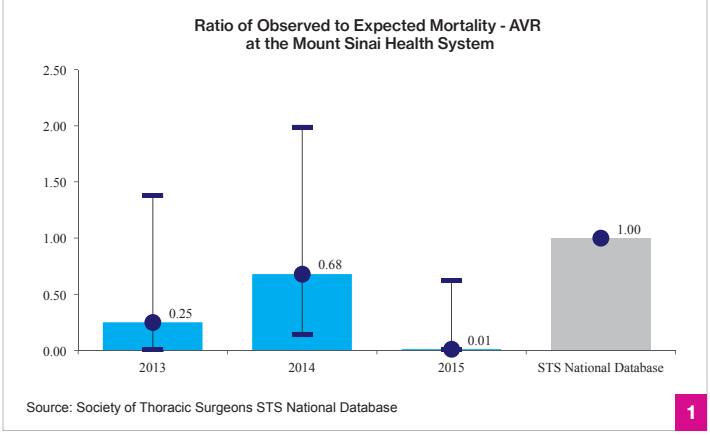
- The results for aortic valve replacement at Mount Sinai again earned a Society of Thoracic Surgery three-star rating, the highest category of quality.

About Dr. Stewart

Allan S. Stewart, MD, is the Director of Aortic Surgery in the Department of Cardiovascular Surgery and Associate Professor of Cardiovascular Surgery at the Icahn School of Medicine at Mount Sinai. Dr. Stewart's clinical research focuses on creating and testing novel treatments and technologies for aortic valve repair and patient mechanical circulatory management during complex aortic surgery. Dr. Stewart pioneered a novel technique in stentless biological aortic root replacement and developed a novel hybrid endovascular procedure for minimally invasive aortic repair, aortic replacement, and treatment of complex aortic aneurysms.

About Dr. Stelzer

Paul Stelzer, MD, is Professor of Cardiovascular Surgery at the Icahn School of Medicine at Mount Sinai. Dr. Stelzer's experience with the Ross procedure – in more than 600 patients – is among the most extensive in the world. Establishing the aortic root replacement modification as the standard for the Ross procedure has been Dr. Stelzer's most significant contribution to the field. He also has extensive experience with the more standard techniques of valve repair and replacement as well as coronary artery surgery, including multiple arterial grafting.



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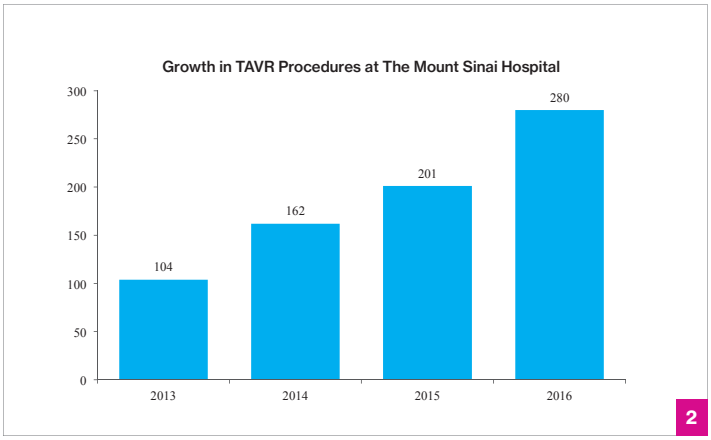

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- The David procedure (valve-sparing root replacement): Mount Sinai is a national leader in conducting this operation, in which the ascending aorta is replaced without harming the native valve. Since 2005, Dr. Stewart has performed more than 350 valve-sparing procedures with excellent results.

- The Ross procedure (a complex alternative for aortic valve-root replacement that involves moving the patient's own pulmonary valve from the right side of the heart to the left and then replacing the pulmonary valve with a human donor pulmonary valve): Dr. Stelzer has performed over 600 Ross procedures in the last 30 years, with exceptionally low mortality and excellent long-term outcomes.

- Minimally invasive surgery: Dr. Stewart leads a team that routinely performs aortic valve replacement, aortic root replacement, and arch replacement without fully opening the breastbone. Typically using a 5 cm incision, this procedure has been shown to be safe and reproducible, and speeds a patient's return to function.

- Research: With robust collaboration with medical geneticists, vascular imaging specialists, and vascular surgeons, and with industry support, the team continues to create tailor-made solutions to individual patient problems. For instance, Mount Sinai is a leading site for investigation of the Thoraflex™ Hybrid graft, an innovative treatment for complex problems of the aortic arch; is working with colleagues in industry to create new devices for the complete endovascular replacement of the aortic root and ascending aorta; and is investigating new means of protecting the brain and spinal cord without resorting to deep hypothermia and circulatory arrest.

- Finally, Dr. Adams serves as the national Co-Primary Investigator for the CoreValve U.S. FDA Pivotal Trial, which has helped establish the safety and efficacy of transcatheter aortic valve replacement as an alternative to open surgery. He first-authored the pivotal trial results in high-risk patients in the *New England Journal of Medicine*, and today patients at Mount Sinai have access to the very latest treatments for aortic valve disease, both by surgical and interventional approaches.

Because of the vast expertise in aortic disease at Mount Sinai Heart, an expeditious diagnosis, a thorough family risk stratification, and an individualized algorithm for care can be created for each patient. Often, a lifelong solution can consist of surveillance with noninvasive imaging, along with lifestyle changes including exercise and blood-pressure control. However, when surgery is required, an intense collaboration affords patients a depth and breadth of surgical experience that is unparalleled in the region. ■

Selected Publications

Adams DH, Popma JJ, Reardon MJ, Yakubov SJ, Coselli JS, Deeb GM, Gleason TG, Buchbinder M, Hermiller J Jr, Kleiman NS, Chetcuti S, Heiser J, Merhi W, Zorn G, Tadros P, Robinson N, Petrossian G, Hughes GC, Harrison JK, Conte J, Maini B, Mumtaz M, Chenoweth S, Oh JK; U.S. CoreValve Clinical Investigators. Transcatheter aortic-valve replacement with a self-expanding prosthesis. N Engl J Med 2014;370(19):1790–8.

Chiang YP, Chikwe J, Moskowitz AJ, Itagaki S, Adams DH, Egorova NN. Survival and long-term outcomes following bioprosthetic vs mechanical aortic valve replacement in patients aged 50 to 69 years. JAMA 2014;312(13):1323–9.

Goldfinger JZ, Halperin JL, Marin ML, Stewart AS, Fuster V. Therapeutic goals in patients with acute aortic dissection: management before surgery. J Am Coll Cardiol 2015;65(15):1601–2.

Goldfinger JZ, Halperin JL, Marin ML, Stewart AS, Fuster V. Thoracic aneurysm and dissection. J Am Coll Cardiol 2014;64(16):1725–39.

Ota T, Yerebaken H, Neely RC, Smith CR, Stewart AS. Short-term outcomes in adult cardiac surgery with the use of del Nido cardioplegia solution. Perfusion 2016;(1):27–33.

1. The quality indicator across the Health System showing observed to expected mortality in isolated aortic valve replacement procedures continues to indicate better than expected performance.

2. Transcatheter aortic valve replacement, a minimally invasive procedure that speeds patients' recovery, has grown sharply in volume at The Mount Sinai Hospital since 2013.

CARDIAC ELECTROPHYSIOLOGY

Cardiac Arrhythmia Services Develops and Delivers Advanced Therapies

Vivek Y. Reddy, MD, *Director of Cardiac Arrhythmia Services for The Mount Sinai Hospital and the Mount Sinai Health System, and Leona M. and Harry B. Helmsley Charitable Trust Professor of Medicine in Cardiac Electrophysiology at the Icahn School of Medicine at Mount Sinai*

Mount Sinai Heart's excellence in arrhythmia services spans New York City, serving patients at the Helmsley Center for Electrophysiology at The Mount Sinai Hospital campus and at the Al-Sabah Arrhythmia Institute at Mount Sinai St. Luke's. The teams have made both sites major patient referral destinations, offering therapies for all types of arrhythmia, from atrial fibrillation to ventricular tachycardia. Patients from around the world seek treatment for heart rhythm disorders at Mount Sinai because of its clinical expertise, leadership in the field of electrophysiology, innovative research, and the latest therapies being tested in clinical trials.

The multidisciplinary team of imaging specialists, cardiac surgeons, nurses, and other clinicians is headed by Vivek Y. Reddy, MD. Through the cardiac electrophysiology fellowship program, Mount Sinai is also training the future leaders in the field.

Atrial Fibrillation

Atrial fibrillation is the most common cardiac arrhythmia, and Mount Sinai is an international referral center for the comprehensive treatment of patients with this condition. The clinical research team under Dr. Reddy recruits participants for trials that offer promising therapies related to the mapping and ablation of atrial fibrillation. For instance, Dr. Reddy was a lead author in a 2015 study in the journal *Circulation* that demonstrated the importance of delivering optimal contact force for effective ablation of atrial fibrillation.

Catheter Ablation

A major concern during catheter ablation for atrial fibrillation is avoidance of injury to the esophagus, which is positioned behind the left atrium. Atrio-esophageal fistula is a rare but devastating complication of catheter ablation that usually results in stroke from air emboli and often results in mortality. Concern about damaging the esophagus can sometimes prevent the delivery of ablation to areas on the posterior left atrium and compromise the effectiveness of the procedure. At Mount Sinai, Dr. Reddy is leading the development and investigation of technology to prevent esophageal injury by deviating the esophagus away from the field of ablative energy. The goal is to maximize not only the safety but also the efficacy of ablation.

Two major referral destinations for patients with heart rhythm disorders.

About Dr. Reddy

Vivek Y. Reddy, MD, is the Director of Cardiac Arrhythmia Services for The Mount Sinai Hospital and the Mount Sinai Health System as well as the Leona M. and Harry B. Helmsley Charitable Trust Professor of Medicine in Cardiac Electrophysiology at the Icahn School of Medicine at Mount Sinai. Dr. Reddy is a leader in the development of advanced therapies for arrhythmias. He works with collaborators worldwide to push forward cardiac electrophysiology and improve on the state of the art. Under his leadership, Mount Sinai is the lead investigator on several multinational clinical trials exploring new arrhythmia procedures and technologies. In 2014, Dr. Reddy implanted inside a patient's heart the world's first miniature leadless pacemaker in the United States at The Mount Sinai Hospital.

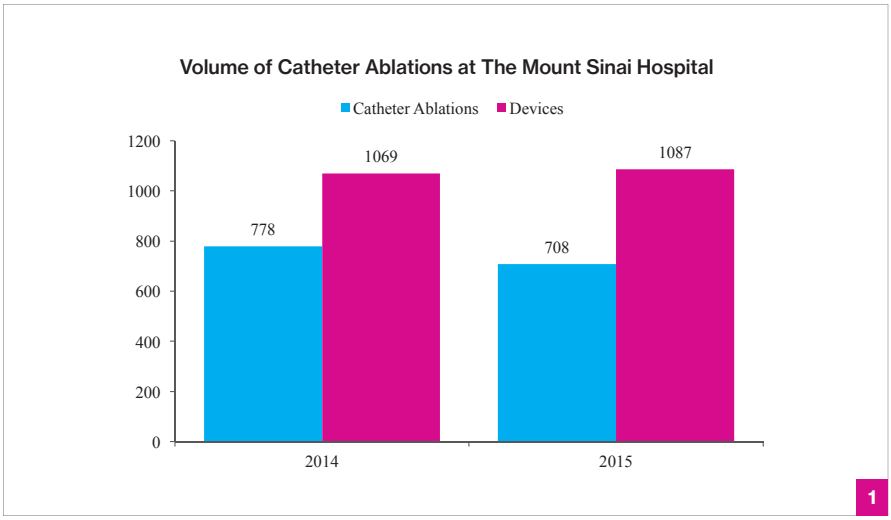
Ventricular Arrhythmia Ablation

Srinivas Dukkipati, MD, Assistant Professor of Medicine (Cardiology) at the Icahn School of Medicine at Mount Sinai and Co-Director of Cardiac Arrhythmia Services, leads the program in ventricular arrhythmia ablation. Mount Sinai has pioneered advanced therapies for ablation of ventricular tachycardia, including the use of percutaneous left ventricular assist devices for patients who require hemodynamic support during their procedures and the use of new technologies to maximize the safety of epicardial access during ablation.

By achieving greater lesion depth with radiofrequency energy, bipolar catheter ablation may offer an alternative for patients who have undergone prior ablation procedures that were unsuccessful due to an intramural site of tachycardia. Dr. Dukkipati is leading a multicenter study of bipolar ablation of ventricular tachycardia with the aim of improving procedural efficacy.

Symposium on Ventricular Arrhythmias

Cardiac Arrhythmia Services remains committed to academic inquiry and fostering collaboration with colleagues worldwide. Dr. Reddy and Dr. Dukkipati collaborate with investigators from the University of Pennsylvania as Co-Directors of the Annual International Symposium on Ventricular Arrhythmias. Now in its 11th year, the Symposium highlights the latest advances in the understanding and treatment of ventricular arrhythmias. In 2016, more than 430 experts from around the world attended the event.



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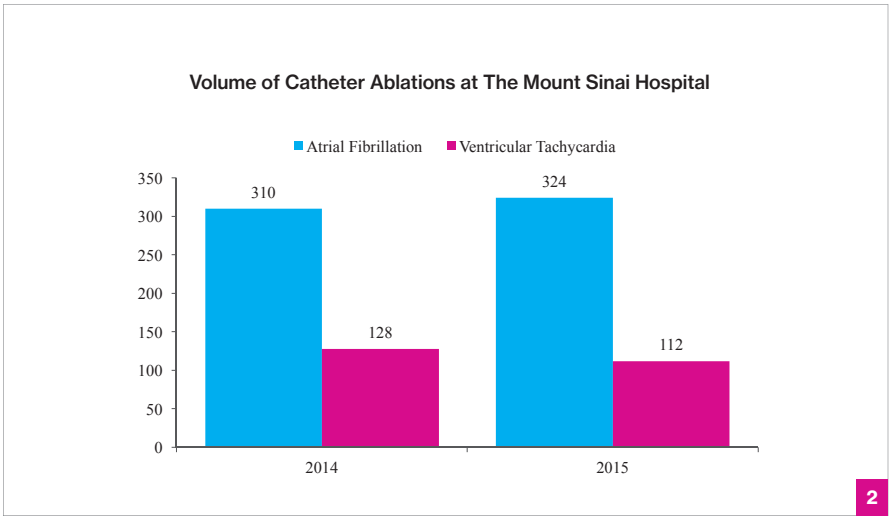

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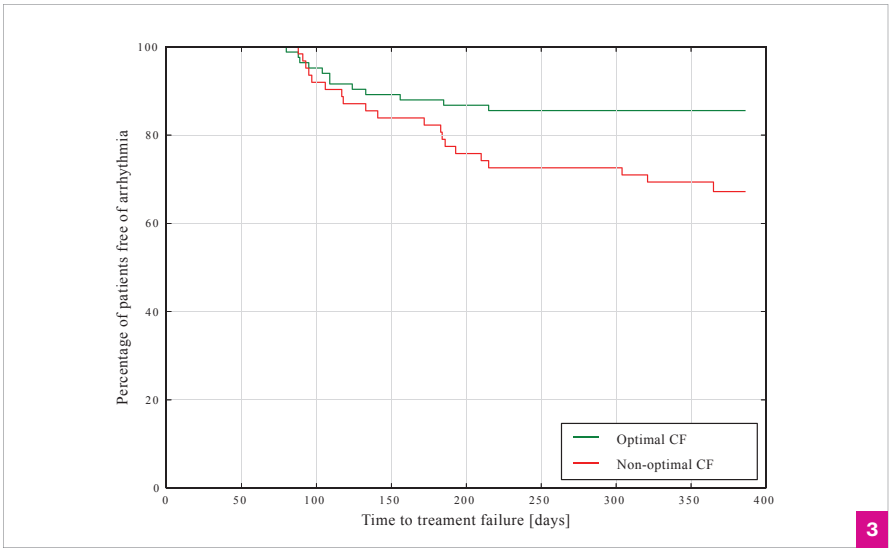

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1. Atrial fibrillation is the most common cardiac arrhythmia, and Mount Sinai is an international referral center for patients with the condition.

2. In treating cardiac arrhythmia, The Mount Sinai Hospital is a leader in advanced therapies, in particular catheter ablations

3. Using a contact force (CF) catheter indicates whether the optimal amount of force is being delivered to tissue, resulting in more effective ablation and a lower rate of recurrence of arrhythmia, according to a study published in 2015 by Vivek Y. Reddy, MD.

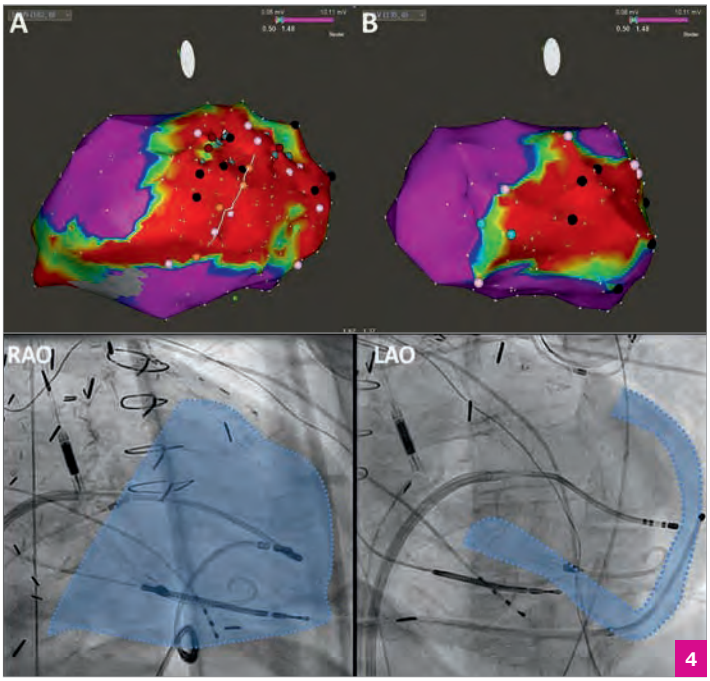
Left atrial appendage closure

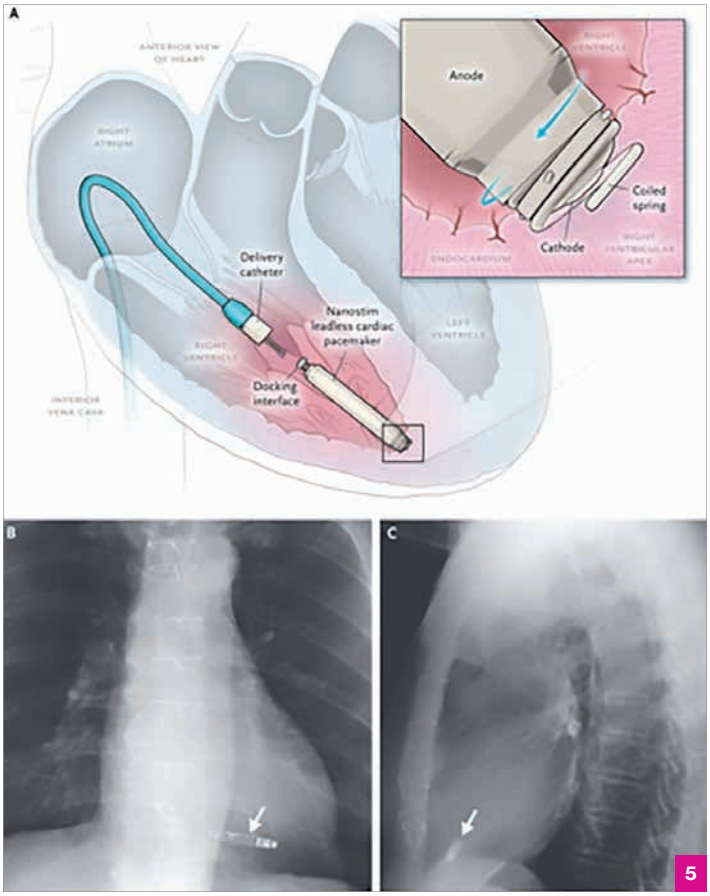
For patients with atrial fibrillation who are at risk for stroke, left atrial appendage closure is an alternative to anticoagulation treatment. The program in left atrial appendage closure at Mount Sinai is one of the most active in the country: in 2015, 86 left atrial appendage closure procedures were performed. Dr. Reddy was a key investigator in two pivotal clinical trials, PREVAIL and PROTECT AF, which established the safety and efficacy of left atrial appendage closure with the WATCHMAN device. The Mount Sinai team is testing the newest technologies in appendage closure to offer more alternatives for patients.

Subcutaneous Implantable Cardioverter Defibrillator and Leadless Permanent Pacemaker

Devices such as the subcutaneous defibrillator and leadless pacemaker are important therapies that may offer advantages compared with devices that use standard intravascular leads. Mount Sinai is an active enrolling site for an international study of subcutaneous defibrillators, PRAETORIAN (Prospective, RAndomizEd comparison of subcuTaneOus and tRansvenous ImplANtable cardioverter-defibrillator therapy). In 2015, 36 subcutaneous defibrillator implants were performed at Mount Sinai.

In 2014 at The Mount Sinai Hospital, Dr. Reddy was the first in the United States to implant a leadless pacemaker in a patient. Dr. Reddy and Dr. Dukkipati are lead authors on a landmark paper, published in the September 2015 issue of *The New England Journal of Medicine*, that established the leadless pacemaker as a viable alternative to standard pacemakers. Thirteen leadless pacemaker implants were performed at Mount Sinai in 2015. ■





4. Bipolar ablation is an advanced therapy under development at Mount Sinai using two catheters to deliver a current through the tissue between them. Above, an electroanatomic map of the left ventricle, with the diseased portion shown in red, and below, an X-ray of the catheters in the left ventricle.

5. The leadless pacemaker is an advanced therapy pioneered at The Mount Sinai Hospital, where Vivek Y. Reddy, MD, was the first in the United States to implant the device in a patient. Above, diagrams of the pacemaker, and below, X-rays of an implanted device.

Selected Publications

Holmes DR Jr, Kar S, Price MJ, Whisenant B, Sievert H, Doshi SK, Huber K, Reddy VY. Prospective randomized evaluation of the Watchman Left Atrial Appendage Closure device in patients with atrial fibrillation versus long-term warfarin therapy: the PREVAIL trial. J Am Coll Cardiol 2014; 64(1):1–12.

Koruth JS, Dukkipati S, Miller MA, Neuzil P, d'Avila A, Reddy VY. Bipolar irrigated radiofrequency ablation: a therapeutic option for refractory intramural atrial and ventricular tachycardia circuits. HeartRhythm 2012; 9(12):1932–41.

Reddy VY, Dukkipati SR, Neuzil P, Natale A, Albenque JP, Kautzner J, Shah D, Michaud G, Wharton M, Harari D, Mahapatra S, Lambert H, Mansour M. Randomized, controlled trial of the safety and effectiveness of a contact force-sensing irrigated catheter for ablation of paroxysmal atrial fibrillation: results of the TactiCath contact force ablation catheter study for atrial fibrillation (TOCCASTAR) study. Circulation 2015;132(10):907–15.

Reddy VY, Exner DV, Cantillon DJ, Doshi R, Bunch TJ, Tomassoni GF, Friedman PA, Estes NA 3rd, Ip J, Niazi I, Plunkitt K, Banker R, Porterfield J, Ip JE, Dukkipati SR; LEADLESS II Study Investigators. Percutaneous implantation of an entirely intracardiac leadless pacemaker. N Engl J Med 2015;373(12):1125–35.

Reddy VY, Sievert H, Halperin J, Doshi SK, Buchbinder M, Neuzil P, Huber K, Whisenant B, Kar S, Swarup V, Gordon N, Holmes D, PROTECT AF Steering Committee and Investigators. Percutaneous left atrial appendage closure vs warfarin for atrial fibrillation: a randomized clinical trial. JAMA 2014;312(19):1988–98.

Team

From left: William Whang, MD; **Marc Miller, MD**; **Jacob Koruth, MD**; **Vivek Y. Reddy, MD,** *Director of Cardiac Arrhythmia Services*; **Srinivas Dukkipati, MD**; **Marie-Noelle Langan, MD**; and **Subbarao Choudry, MD.**

IMAGING



Comprehensive Range of Imaging And Research by Leading Investigators

Jagat Narula, MD, PhD, MACC, *Director of Cardiovascular Imaging for the Mount Sinai Health System and Professor of Medicine (Cardiology) and Radiology, Icahn School of Medicine at Mount Sinai;* **Valentin Fuster, MD, PhD,** *Director of Mount Sinai Heart;* and **Javier Sanz Salvo, MD,** *Director of Cardiac MR/CT in the Cardiovascular Institute at The Mount Sinai Hospital and Associate Professor of Medicine (Cardiology) and Radiology*

Advances in imaging technology have sparked fundamental changes in the approach to cardiac care. At Mount Sinai Heart, the Cardiovascular Imaging Center provides insight into the progression of cardiovascular disease that enables physicians to identify conditions at earlier stages and with greater accuracy. The Center houses state-of-the-art diagnostic equipment, with imaging tools that can discover medical problems that were previously undetectable using conventional methods of diagnosis.

Among the diagnostic technologies are:

- Cardiac computed tomography, including coronary angiography and calcium scoring
- Cardiovascular magnetic resonance imaging
- Echocardiography: 2D and 3D, stress, contrast, and transesophageal
- Cardiac positron emission tomography
- Vascular CT and magnetic resonance (MR) angiography
- Vascular ultrasound
- Nuclear cardiology.

In his quest to modernize cardiovascular imaging services, Valentin Fuster, MD, PhD, recruited Jagat Narula, MD, PhD, MACC, to Mount Sinai Heart in 2011. Dr. Narula was subsequently asked to take over as Chief of the Division of Cardiology at Mount Sinai West and Mount Sinai St. Luke's.

Working with Dr. Fuster, Dr. Narula has galvanized imaging services across the Mount Sinai Health System. The main campus alone performs 25,000 echo procedures, 5,000 coronary or vascular CT angiograms, 1,000 magnetic resonance and 5,000 radionuclide imaging examinations. These numbers make Mount Sinai one of the most comprehensive imaging programs in the country. Working with Annapoorna Kini, MD, and Samin K. Sharma, MD, in intravascular imaging and collaborating with genomic investigation in the laboratory of Joel Dudley, PhD, Dr. Narula has helped bring national recognition to the translational research taking place in Mount Sinai's Catheterization Laboratory.

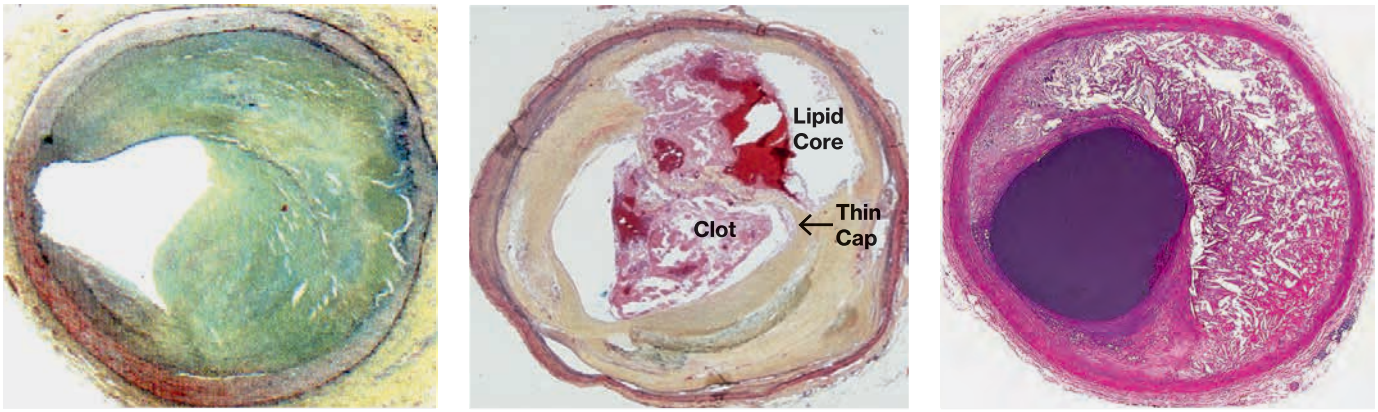
Working closely with Dr. Narula is Javier Sanz Salvo, MD, Director of Cardiac MR/CT in the Zena and Michael A. Wiener Cardiovascular Institute at The Mount Sinai Hospital. Dr. Sanz has performed more than 7,000 cardiovascular MRI and 15,000 cardiovascular CT studies, has presented in multiple scientific meetings and publications, and is a member of the Certification Board of Cardiovascular Computed Tomography Exam Item Writing and Exam Review, composed of experts who determine the qualifications of cardiac CT readers in the United States.

About Dr. Narula

Jagat Narula, MD, PhD, MACC, is the Director of the Cardiovascular Imaging Program and Philip J. and Harriet L. Goodhart Professor of Medicine (Cardiology) and Radiology, and Associate Dean at The Arnhold Institute of Global Health at the Icahn School of Medicine at Mount Sinai. Dr. Narula is Editor in Chief of *JACC: Cardiovascular Imaging*. He has specifically contributed to two major areas: heart muscle cell apoptosis in heart failure, and lipid-rich atherosclerotic plaques that are susceptible to rupture and acute coronary events.

About Dr. Sanz

Javier Sanz Salvo, MD, is the Director of Cardiac MR/CT in the Cardiovascular Institute at The Mount Sinai Hospital and an Associate Professor of Medicine (Cardiology) and Radiology at the Icahn School of Medicine at Mount Sinai. Dr. Sanz has extensive experience in the clinical use of cardiac imaging, specifically MR and CT. In the past year, Dr. Sanz became Director of Imaging of the Progression of Early Subclinical Atherosclerosis (PESA) study, a large prospective research study among approximately 4,000 individuals being performed in the Centro Nacional de Investigaciones Cardiovasculares in Madrid, Spain.



Stable Plaque | Ruptured Plaque | High-Risk Plaque

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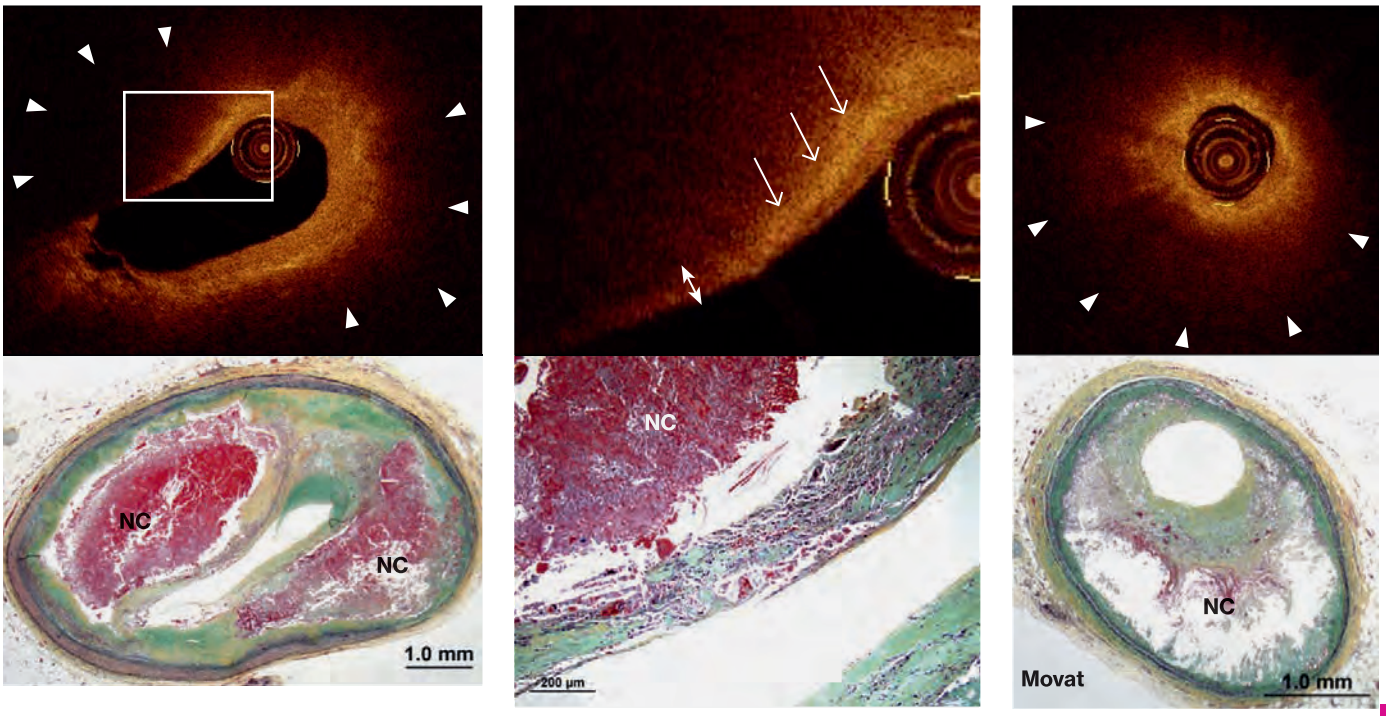

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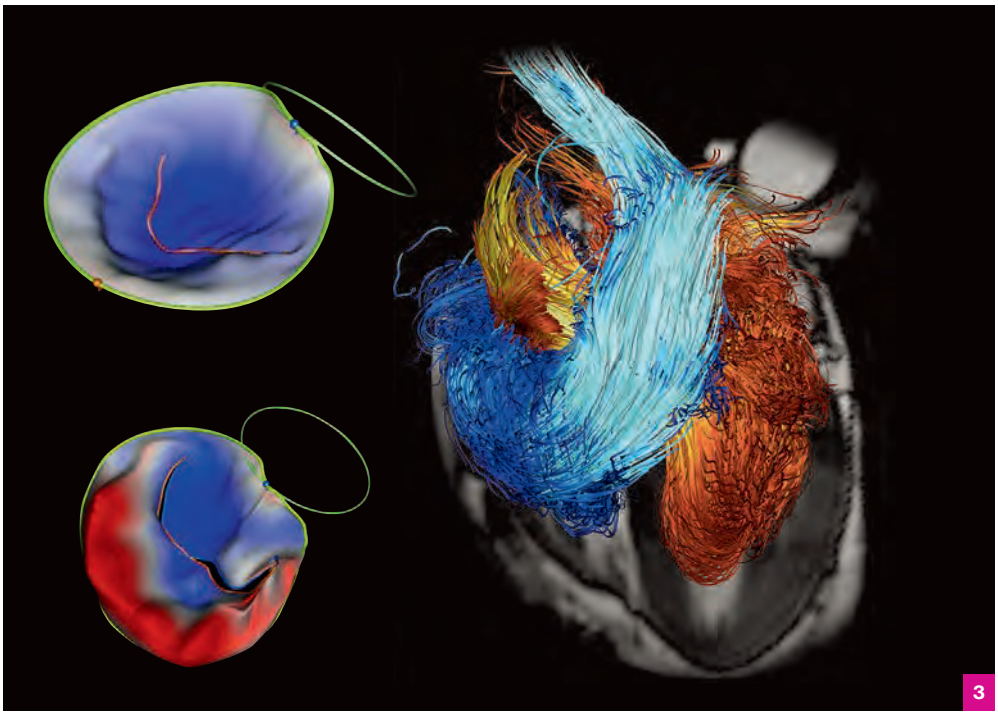
The Cardiac MR/CT Program is composed of a team of three cardiologists, two radiologists, two advanced imaging fellows, three technologists, one nurse, and one administrative assistant. Dr. Sanz's team performs studies in many types of complex cases, such as planning of structural interventions, follow-up of ventricular assist devices, and advanced tissue characterization.

The combination of multidisciplinary expertise (including multimodality imaging, cardiovascular and thoracic evaluation, study of acquired and congenital heart disease, and stress testing), state-of-the-art facilities and equipment, and a large volume of procedures in a wide array of complex diseases makes Mount Sinai an unparalleled center for cardiovascular imaging care. ■

1. Fatal lesions in the arteries of the heart often carry a large volume of lipid material under a thin, fibrous cap that can rupture, produce a clot, and result in a cardiac event. If a cap is intact, the patient is still at risk of a plaque rupture and heart attack. Imaging helps identify high-risk patients and high-risk plaques.

2. Placing optical coherence tomography catheters directly in the artery is the only imaging technique that can define the thickness of the fibrous cap, indicated with white arrows, which can rupture at less than 55 microns. The lower row of images shows the thick cap of a stable lesion.



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Mummies Give Insight Into Atherosclerosis And Global Cardiovascular Health

For years, Jagat Narula, MD, PhD, MACC, researched the length, breadth, and depth of atherosclerosis. Now insights from research into ancient mummies have led him to add a fourth dimension: time. This research showed that the risk factors for heart disease are the same now as they were 4,000 years ago and that it is not an inevitable disease.

Hypothesizing that heart disease is "the curse of modernization," Dr. Narula and researchers known as the Horus Group studied the cardiovascular health of mummies from four geographic regions and found heart disease in mummies with the same risk factors. Through whole-body calcium scanning, the researchers found that 34 percent of Egyptian mummies—elites who were sedentary and had high-fat diets—had coronary calcifications. Similarly, 25 percent of the Peruvian mummies examined by researchers had coronary disease. These were farmers or peasants who had mostly vegetarian diets and exercised but were exposed to smoke from cooking over an open fire.

The researchers found that heart disease is significantly postponed in populations that have few or no risk factors, as in Indian and Bolivian subpopulations they studied that are vegetarian, exercise, meditate, and do not smoke. This suggests that the promotion of global cardiovascular wellness through public health screenings and education about the risk factors for heart disease could help eradicate coronary artery disease. ■

4

3. In treating cardiac arrhythmia, The Mount Sinai Hospital is a leader in advanced therapies, in particular catheter ablations. Echocardiographic images show mitral valves that are normal (above, left) and billowing (below, left). At right, magnetic resonance imaging shows normal and aberrant blood flow. Vector velocity imaging has also become feasible with echocardiography.

4. The Horus Group of cardiologists uses imaging techniques to identify the extent of cardiovascular disease in mummies during an expedition in Cairo, Egypt.

Imaging Institute Develops a New Generation of Techniques

Zahi A. Fayad, PhD, *Mount Sinai Professor in Medical Imaging and Bioengineering at the Icahn School of Medicine at Mount Sinai*

The Translational and Molecular Imaging Institute (TMII), headed by Zahi A. Fayad, PhD, is focused on developing and using noninvasive imaging methods that allow the early detection, prevention, and treatment of cardiovascular disease. The Institute serves as a research catalyst for a new generation of translational and molecular imaging methodologies. It offers researchers efficient, cost-effective services that they need to perform commonly used imaging tests, providing expertise for developing and validating new procedures and encouraging interdisciplinary collaborations that help close the gaps between clinical and preclinical studies. TMII has more than 50 team members with expertise in all aspects of translational imaging research, from image acquisition to analysis.

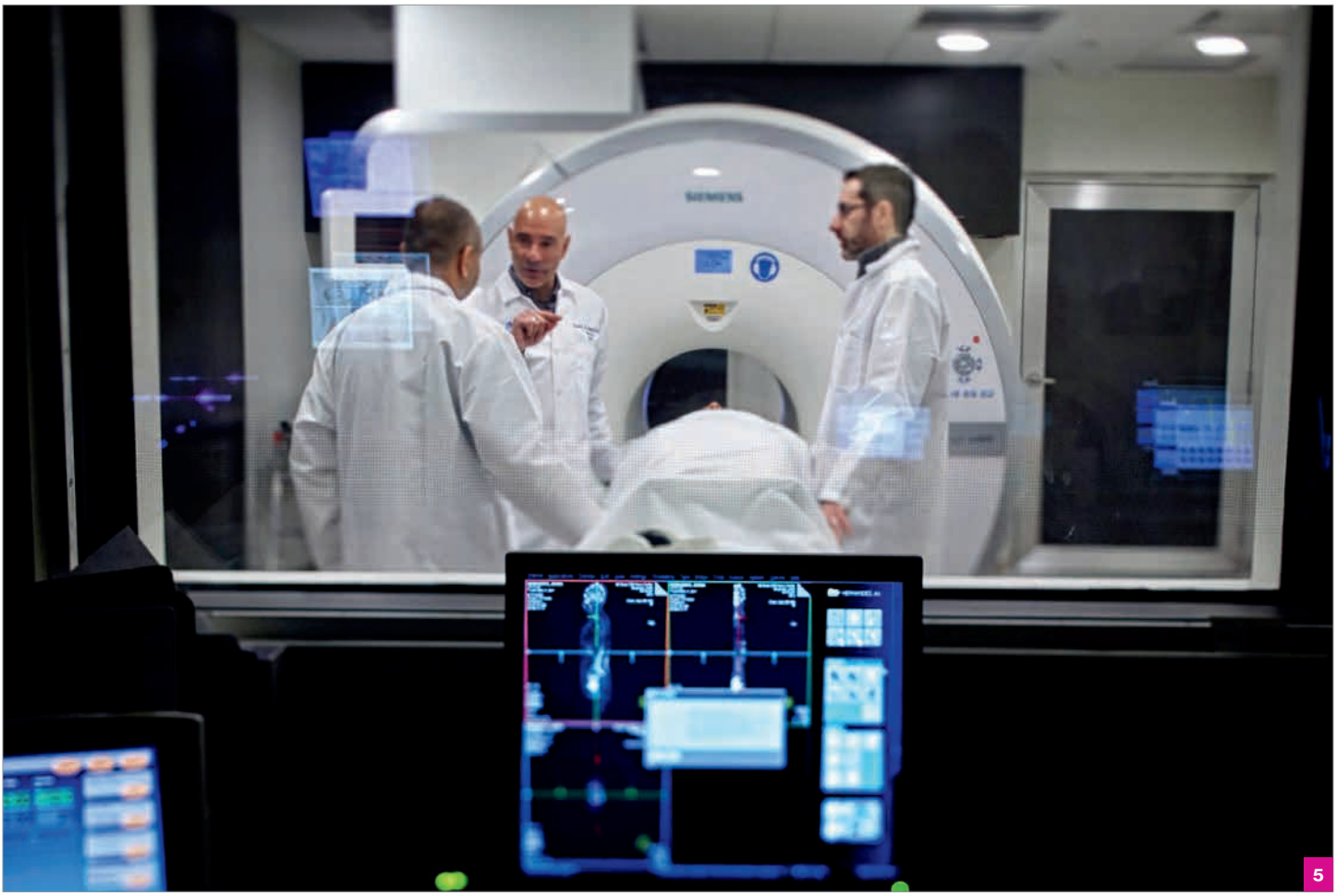
Mount Sinai pioneered the use of magnetic resonance imaging (MRI) to detect, in a noninvasive way, hidden plaque buildup within the arterial wall. Building on that work, collaborative research is now combining cardiovascular MRI with other technologies, especially positron emission tomography (PET) scanning, to investigate the lumen and the vessel wall noninvasively.

Dr. Fayad, who is Director of both TMII and Cardiovascular Imaging Research at the Icahn School of Medicine at Mount Sinai, is a world leader in the development and use of multimodality cardiovascular imaging. He has also developed methods for targeted drug delivery to improve the treatment of cardiovascular disease, and he holds multiple patents in imaging and nanomedicine.

In 2013, Mount Sinai and TMII entered into a strategic partnership with Siemens Medical Systems to support efforts in translational research. Housed in a 20,000-square-foot space in the Leon and Norma Hess Center for Science and Medicine are a number of Siemens systems that include, among others, a whole-body 7T MR scanner, a fully integrated simultaneous MR(3T)/PET system, and a novel dual-source CT for faster and lower-dose imaging. Mount Sinai is specifically interested in PET/MR because the combination provides an advanced and simultaneous understanding of the processes taking place in the vascular beds, the heart, and other organs, automatically combining functional, molecular/cellular, and anatomical information and at the same time reducing the dose of radiation to the patient and enabling a systems approach to assessing health and disease. ■

About Dr. Fayad

Zahi A. Fayad, PhD, is the Mount Sinai Professor in Medical Imaging and Bioengineering at the Icahn School of Medicine at Mount Sinai. He is the founding Director of the Translational and Molecular Imaging Institute and Professor of Medicine (Cardiology) and Radiology. Dr. Fayad is the Principal Investigator of five federal grants and contracts funded by the National Institutes of Health Heart, Lung, and Blood Institute and National Institute of Biomedical Imaging and Bioimaging. His discipline-bridging research – in engineering, biology, and clinical and preclinical investigations – is dedicated to the prevention of cardiovascular disease, with seminal contributions to multimodality biomedical imaging (MR, CT, PET, and PET/MR) and nanomedicine.



5. Zahi A. Fayad, PhD, center, with the PET/MR scanner located in the Translational and Molecular Imaging Institute at the Leon and Norma Hess Center for Science and Medicine at the Icahn School of Medicine at Mount Sinai. The PET/MR system enables the study of the whole cardiovascular system at the molecular level while providing whole-body anatomical and functional assessment simultaneously.

Team

From left: Gina LaRocca, MD, FACC; **Zahi A. Fayad, PhD,** *Director of the Translational and Molecular Imaging Institute*; **Lori B. Croft, MD,** *Director of Nuclear Medicine*; **Valentin Fuster, MD, PhD,** *Director of Mount Sinai Heart*; **Jagat Narula, MD, PhD, MACC,** *Director of the Cardiovascular Imaging Program*; **Farooq A. Chaudhry, MD,** *Director of the Echocardiography Laboratory*; **Martin Goldman, MD.**

HEART FAILURE

Extending and Enhancing Life Through Heart Transplantation, Support Devices, and Focused Care

Anelechi Anyanwu, MD, *Professor and Vice Chair of the Department of Cardiovascular Surgery, and Surgical Director, Heart Transplantation and Mechanical Circulatory Support for the Mount Sinai Health System,*
and **Sean P. Pinney, MD,** *Associate Professor of Medicine (Cardiology) and Director of Heart Failure and Transplantation*

The mission of the Advanced Heart Failure and Transplantation Program is to extend and improve the quality of life of patients suffering from advanced heart disease. The program is dedicated to seeking therapeutic breakthroughs, improving clinical outcomes, and enhancing health care quality. In a multidisciplinary approach, the team of cardiologists, cardiac surgeons, nurses, and social workers collaborates to offer each patient personalized health-management plans and the full spectrum of heart failure clinical services. The program's specialists have advanced training, years of clinical experience, and access to innovative treatments.

The team is led by Anelechi Anyanwu, MD, Professor and Vice Chair of the Department of Cardiovascular Surgery, and Sean P. Pinney, MD, Associate Professor of Medicine (Cardiology) and Director of Heart Failure and Transplantation for the Mount Sinai Health System. As leaders of the Advanced Heart Failure team, the physicians have introduced new mechanical devices for circulatory support, including the Total Artificial Heart.

Advanced Heart Failure

The team specializes in treating patients with heart failure arising from a spectrum of inherited and acquired forms of heart disease. Specialists provide expert care to patients with ischemic and nonischemic forms of cardiomyopathy. Because Mount Sinai is a mitral valve reference center, one of only a few nationwide, the hospital has developed particular expertise in managing patients with advanced stages of valvular or ischemic heart disease complicated by heart failure, pulmonary hypertension, or right heart failure. Specialized clinics diagnose and manage patients with inherited cardiomyopathies, including hypertrophic and LV noncompaction cardiomyopathy. And there are clinical programs designed to manage diastolic heart failure, cardiac amyloidosis, adult congenital heart disease, and cardio-oncology. The program also offers the entire range of medical, catheter-based, electrophysiological, and surgical interventions for advanced heart failure.

Accomplishments in 2016:

- 3,300 outpatient visits and 400 new patients evaluated for advanced heart failure and pulmonary hypertension
- Heart failure survival rates in excess of national averages
- Low 15 percent readmission rate for patients in the heart failure disease-management program

About Dr. Anyanwu

Anelechi Anyanwu, MD, is Professor and Vice Chair of the Department of Cardiovascular Surgery in the Icahn School of Medicine at Mount Sinai and Surgical Director, Heart Transplantation and Mechanical Circulatory Support, for the Mount Sinai Health System. Dr. Anyanwu is trained in all aspects of thoracic transplantation, including heart transplantation, heterotopic heart transplantation, heart-lung transplantation, domino heart transplantation, and lung transplantation. His other areas of specialized training include multiple arterial revascularization using bilateral skeletonized internal mammary artery grafts. In addition to his expertise in transplantation and mechanical assistance, Dr. Anyanwu is a senior member of the mitral team with expertise in all areas of valve reconstruction.

About Dr. Pinney

Sean P. Pinney, MD, Associate Professor of Medicine (Cardiology) and Director of Heart Failure and Transplantation, is an active clinical researcher who has led both NIH- and industry-sponsored trials in the areas of heart failure, cardiac transplantation, and mechanical circulatory support. He has codirected the Heart Failure Society's review course in advanced heart failure and served as editorial team leader for the acc.org heart failure clinical topic collection. He serves on the ACC Heart Failure and Transplant Committee and the International Society for Heart and Lung Transplantation's I2C2 committee, and he is past president of the New York Cardiothoracic Transplant Consortium.

- Expanded the CardioMEMS™ heart failure monitoring system and sensible fluid management programs.

Heart Transplantation

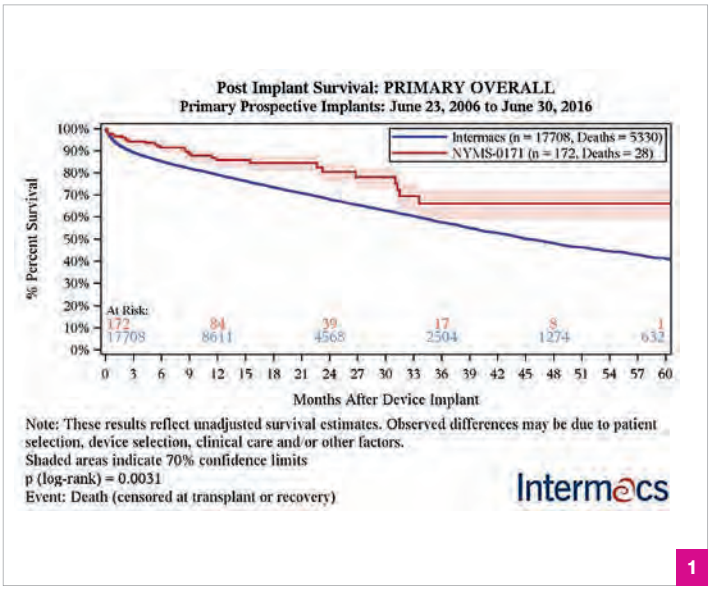
Mount Sinai launched its heart transplant program in 1989 and has since performed more than 500 transplants, achieving excellent survival rates. The program is one of the nation's largest and has a growing wait list, but further growth in transplant volume remains restricted by a limited donor supply. Innovations launched at Mount Sinai include the use of tacrolimus monotherapy, intravascular ultrasound for cardiac allograft vasculopathy, and the early adoption of gene expression profiling as a rejection screening tool, eliminating invasive, painful biopsies for a majority of patients. Mount Sinai has relaxed the traditional stringent inclusion criteria and offers transplantation to patients who would typically not have that option, such as elderly patients, patients with human immunodeficiency virus, patients with failing previous transplants, and patients with a limited ability to pay.

Accomplishments in 2016:

- One-year survival rate of 87 percent
- Projected volume of 30 transplants, the highest ever at this center
- Average hospital length of stay fewer than 14 days.

Mechanical Circulatory Support

Mount Sinai is home to one of the country's largest mechanical circulatory support programs. Conceived as an integrated partnership between cardiology and cardiovascular surgery, this program has emerged as a center of excellence with volumes and outcomes that are among the best in the nation. The program's growth parallels that of newer-generation continuous flow left ventricular assist devices, which are implanted to replace the major functions of the left side of the heart in patients with advanced heart failure due to severe weakness of the heart muscle. These small devices consist of a single rotating element suspended either by electromagnets or contact bearings within a metal housing and can keep patients alive for several years. They can generate near physiologic levels of blood flow and can restore patients to normal activity levels with good quality of life. Mount Sinai is the only program in New York actively offering patients the Total Artificial Heart. This device, a descendent of the Jarvik-7, replaces the pumping function of the heart and is used for patients with special indications, including irreversible severe damage of both ventricles of the heart, refractory ventricular arrhythmias, or a need for a repeat transplantation. Mount Sinai surgeons have implanted more than 20 such devices and have the most experience in the Northeast. Mount Sinai also has an active temporary support program, which includes the use of peripheral assist devices, temporary surgical support devices, and extracorporeal membrane oxygenation for patients who develop acute cardiogenic shock or who suffer unexpected cardiac arrest. Mount Sinai is proud to offer an all-inclusive program, giving all patients consideration regardless of severity of illness, high risk of mortality, socioeconomic status, social history, technical or logistic barriers, or age. The team believes that all patients have a right to survival and has successfully offered life-saving therapy



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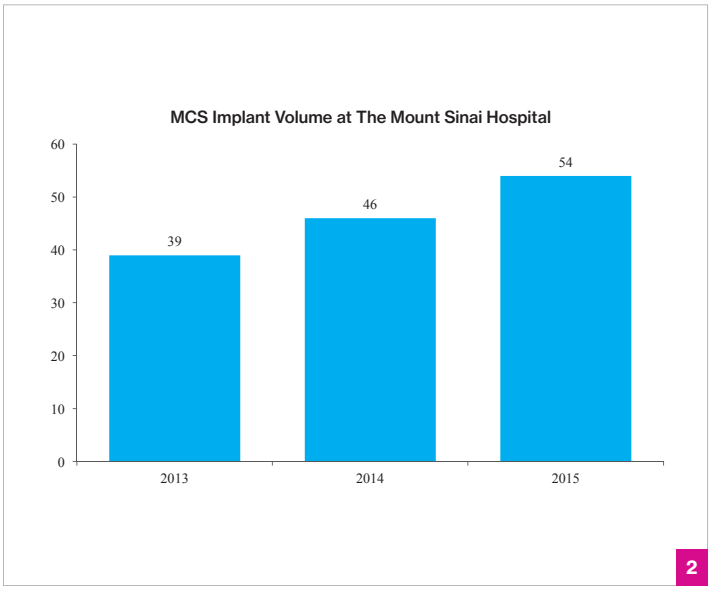

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1. Patients receiving mechanical circulatory support devices at The Mount Sinai Hospital had survival rates that significantly exceeded national averages. The one-month survival rate was 97 percent; the six-month rate was 91 percent; and the one-year rate was 86 percent.

2. Mechanical circulatory support (MCS) device implants have consistently increased since the program's inception in 2004. The growth of the program accelerated with the use of the Total Artificial Heart and the adoption of continuous flow left ventricular assist devices as either a bridge or an alternative to heart transplantation.

to several patients who were turned down by neighboring or distant programs.

Mount Sinai also has an active pediatric mechanical circulatory support program, led by Khanh H. Nguyen, MD, which offers hope for children with complex congenital or acquired heart disease who do not have other curative options.

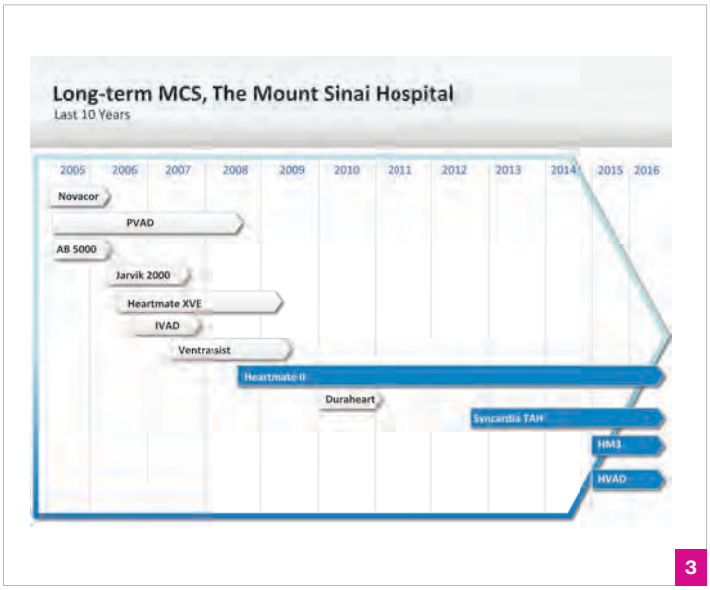
Accomplishments in 2016:

- Survival rates for patients who received mechanical circulatory support devices of 97 percent after one month, 91 percent at six months, and 86 percent after one year
- More than 100 patients on long-term support
- Implant volume rose to more than 50 devices
- Total artificial heart survival of 100 percent at one month and 70 percent at one year.

Innovations and Research

The heart failure team has been at the forefront of innovation, research, and education in advanced heart failure. The Mount Sinai team has pioneered approaches for less invasive implantation of left ventricular assist devices (LVADs). In addition, it has challenged several conventional approaches to LVAD management. It has introduced new paradigms for future care, including the primary use of these devices in cardiogenic shock, modification in management of defibrillators in LVAD patients, use of LVADs as an alternative to conventional surgical procedures with limited prognosis, and as a way to manage concurrent valvular disease. The team has participated in trials evaluating several novel and investigational mechanical circulatory devices. Data from the most recent device (HeartMate 3®) were presented at the American Heart Association in November 2016. A key element of the team's research has been its focus on the human aspects of living with a ventricular assist device. The team has studied the impact of these mechanical pumps on patients and their caregivers and the influence on quality of life. For heart transplantation, Mount Sinai has simplified immunosuppression regimes to limit patients' exposure to high doses of potentially harmful potent drugs. Under the leadership of Dr. Pinney and Anuradha Lala, MD, Director of Heart Failure Research, the team held its first continuing medical education symposium in Advanced Heart Failure, which attracted more than 225 delegates, helping to update practitioners and improve local and regional care of patients.

Dr. Anyanwu, Dr. Pinney, and their team are international thought leaders in the field and are actively involved in several national and international academic organizations, contributing to peer-review, organizational, consensus, and educational activities. ■



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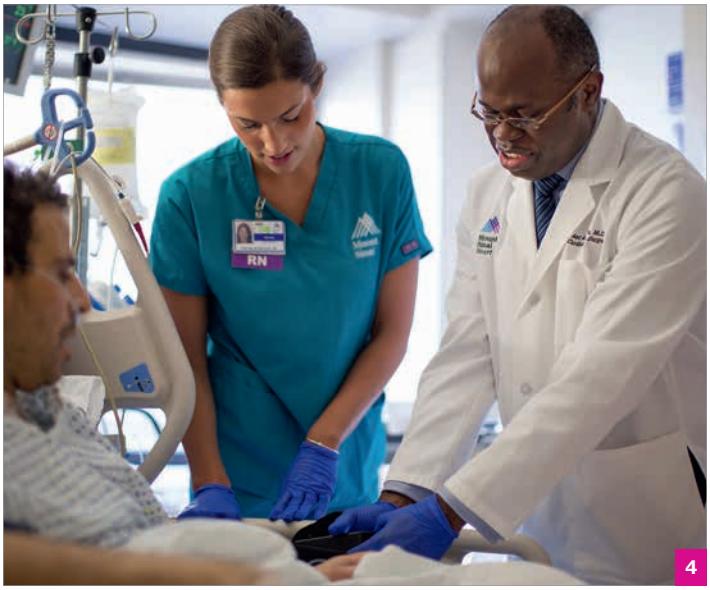

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3. An evolution of device technology has progressed from large-volume displacement pumps to smaller continuous flow left ventricular assist devices. Devices shaded in blue are in current use, including the Total Artificial Heart.

4. Thirty heart transplants were performed in 2016 at The Mount Sinai Hospital in one of the nation's largest programs. Anelechi Anyanwu, MD, with Rachael Bischoff, RN, at the bedside of a transplant patient.

Clinical Trials

The team is actively enrolling in the following clinical trials:
International EXPAND Heart Clinical Trial NCT02323321 – International Trial to Evaluate the Safety and Effectiveness of The Portable Organ Care System (OCS™) Heart For Preserving and Assessing Expanded Criteria Donor Hearts for Transplantation

MOMENTUM3 Clinical Access Protocol NCT02892955 – Evaluating use of the HeartMate 3 Magnetically Levitated Left Ventricular Assist Device

PIONEER-HF: comParIson Of Sacubitril/valsartaN Versus Enalapril on Effect on ntpRo-bnp in Patients Stabilized From an Acute Heart Failure Episode NCT02554890

REDUCE LAP Heart Failure Trial NCT01913613

Sensible Medical Innovations Lung fLuid Status Monitor Allows rEducing Readmission Rate of Heart Failure Patients (SMILE™) NCT02448342

SOPRANO NCT02554903 – Clinical Study to Assess the Efficacy and Safety of Macitentan in Patients With Pulmonary Hypertension After Left Ventricular Assist Device Implantation

Selected Publications

Benton CR, Sayer G, Nair AP, Ashley K, Domanski MJ, Henzlova MJ, Anyanwu AC, Pinney SP. Left ventricular assist devices improve functional class without normalizing peak oxygen consumption. ASAIO J 2015;61(3):237–43.

Chikwe J, Itagaki S, Anyanwu A, Adams DH. Impact of concomitant tricuspid annuloplasty on tricuspid regurgitation, right ventricular function, and pulmonary artery hypertension after repair of mitral valve prolapse. J Am Coll Cardiol 2015;65(18):1931–8.

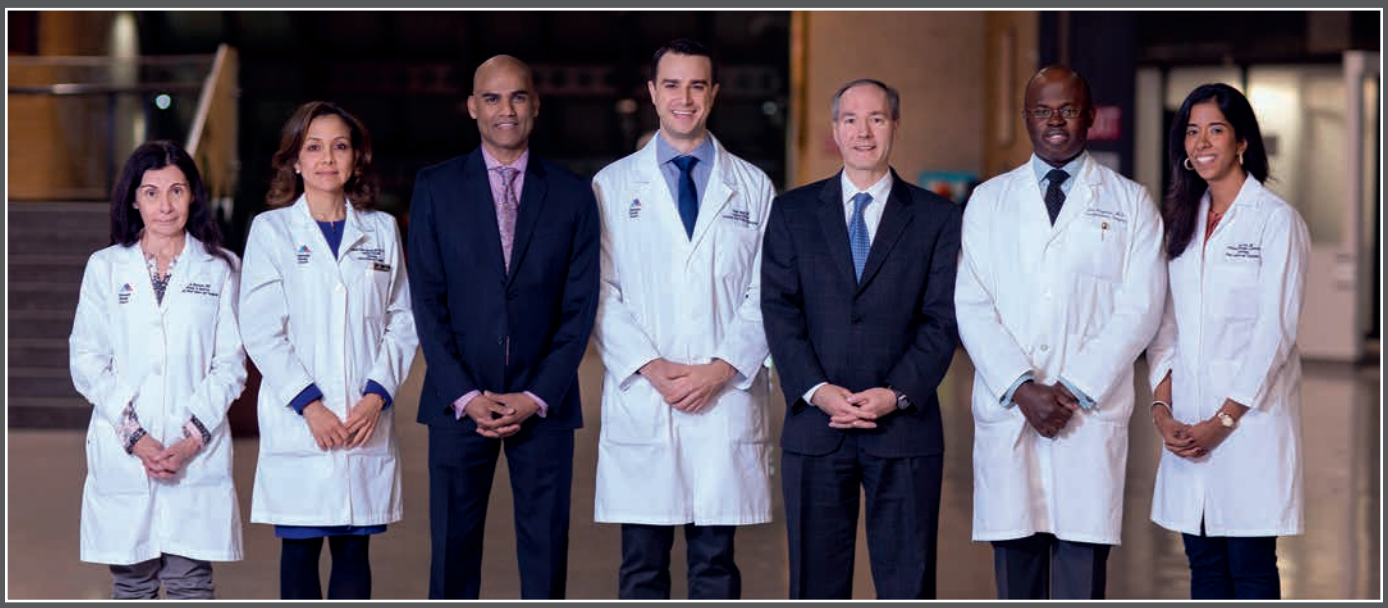
Enriquez AD, Calenda B, Gandhi PU, Nair AP, Anyanwu AC, Pinney SP. Clinical impact of atrial fibrillation in patients with the HeartMate II left ventricular assist device. J Am Coll Cardiol 2014;64(18):1883–90.

Lala A, McNulty SE, Mentz RJ, et al. Relief and recurrence of congestion during and after hospitalization for acute heart failure: insights from diuretic optimization strategy evaluation in acute decompensated heart failure (DOSE-AHF) and cardiorenal rescue study in acute decompensated heart failure (CARESS-HF). Circ Heart Fail 2015;8(4):741–8.

Lala A, Pinney SP. Recognizing pulmonary hypertension and right ventricular dysfunction in heart failure. Prog Cardiovasc Dis 2016;58(4):416–4.

Park CS, Akhabue E, Bansal M, Marks J, Salem Omar AM, Pinney SP, Anyanwu A, Chaudhry F, Narula J, Sengupta PP. Dynamic changes in LV radius as a marker of septal configuration for predicting RV failure following LVAD implantation. JACC Cardiovasc Imaging 2016 doi: 10.1016/j.jcmg.2016.04.002

Pawale A, Plotkina I, Anyanwu AC. Technique for implantation of HeartMate II left ventricular assist device with concurrent mitral and tricuspid valve repair. Ann Cardiothorac Surg 2014;3(5):532–4.



Team

From left: Donna M. Mancini, MD; **Johanna Contreras, MD**; **Radha Gopalan, MD**; **Noah Moss, MD**; **Sean Pinney, MD,** *Director of Heart Failure and Transplantation*; **Analechi Anyanwu, MD,** *Vice Chair of the Department of Cardiovascular Surgery*; **Anuradha Lala, MD,** *Director of Heart Failure Research.*

REPORT ON

TRANSLATIONAL RESEARCH/GENE REGENERATIVE THERAPY

Translational Research Is Exploring Novel Therapies and a New Depth of Inquiry

Roger J. Hajjar, MD, *Director, Cardiovascular Research Center; Arthur and Janet C. Ross Professor of Medicine, Icahn School of Medicine at Mount Sinai*

In a rapidly changing field, the Cardiovascular Research Center (CVRC) at the Icahn School of Medicine at Mount Sinai is making important strides in diagnosis, treatment, and prevention of heart disease. Cardiovascular gene therapy once seemed little more than an unsubstantiated promise, but today genetic engineering is being used to create potential therapies that heal the failing heart and improve the lives of the most severely afflicted cardiac patients.

The Center's Director is Roger J. Hajjar, MD, the Arthur and Janet C. Ross Professor of Medicine at the Icahn School of Medicine, an international leader in the field of gene therapy for heart failure. Its researchers are studying the basic mechanisms of cardiovascular disease and exploring personalized medicine based on identifying genomic predictors. The collaborative resources found across the Mount Sinai Health System create a unique environment for translational research that is patient-driven, responsive, and targeted.

The Center has a team of lead investigators and researchers working across platforms to investigate stem cell biology, tissue engineering, vector biology, electrophysiology, vascular diseases, diabetes, imaging, and clinical trials. The collaboration and shared vision have led the Center to novel therapies and a new depth of inquiry that is translating into real progress in the field.

The CVRC was created in 2007 and has grown to include roughly 70 members, including investigators, postdoctoral fellows, research scientists, technicians, and students. In 2016, its total National Institutes of Health funding increased to more than $14 million, and it received two Transatlantic Fondation Leducq grants, a Specialized Research Center Grant (P50) from the National Institutes of Health, a Department of Defense Concept Award, and an NIH Shared Instrumentation Grant (S10).

The faculty has a broad range of interests, with areas of research including gene therapy for heart failure, gene-based therapies for arrhythmias, tissue engineering, 3D bioprinting, post-translational modifications in heart failure, exosomes in cardiac repair, modified RNA as a novel platform for cardiac

About Dr. Hajjar

Roger J. Hajjar, MD, is the Director of the Cardiovascular Research Center and the Arthur and Janet C. Ross Professor of Medicine at the Icahn School of Medicine at Mount Sinai. Dr. Hajjar is an internationally renowned leader in cardiac gene therapy for heart failure. His laboratory validated the cardiac sarcoplasmic reticulum calcium ATPase pump (SERCA2a) as a target in heart failure and developed methodologies for cardiac-directed gene therapy that are used by investigators throughout the world. Dr. Hajjar has won numerous awards, including the Young Investigator Award of the American Heart Association and the Mount Sinai Dean's award for Excellence in Translational Science.

regeneration, diabetic cardiomyopathy, adeno-associated vector biology, fibromuscular dysplasia, and large-animal models of cardiovascular diseases.

The vision of the CVRC is threefold: to create a physical infrastructure populated by investigators pursuing innovative cardiovascular research, to nurture early-career translational and clinical investigators, and to initiate new training and career-development programs while reaching out to high school and undergraduate students from underrepresented minorities in the area surrounding Mount Sinai. The training program, coupled with a Molecular and Cellular Cardiology T32 Training Grant through the National Heart, Lung, and Blood Institute, reached its 20th year in 2016 and supports eight postdoctoral trainees each year. The T32 program is housed in the CVRC but is composed of faculty preceptors in several departments and provides support to postdoctoral researchers.

Hajjar Laboratory

The laboratory led by Dr. Hajjar is focused on developing novel therapies for the treatment of heart failure. The group studies calcium cycling abnormalities in various models of heart failure and has developed new strategies to improve intracellular dynamics and the function of the whole heart. Its areas of research include:

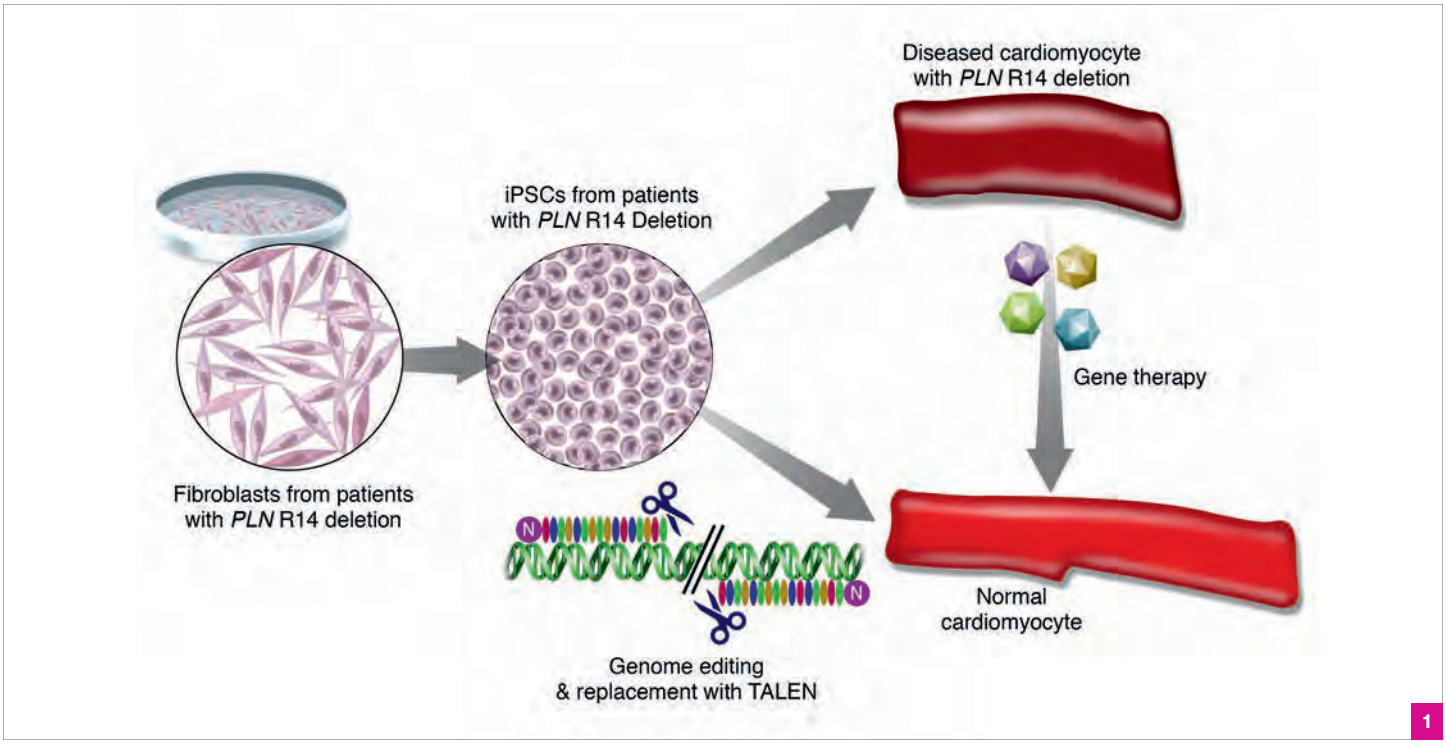
Gene Therapy for Heart Failure

The Hajjar Laboratory developed the world's first clinically tested platform for a gene-therapy vector for the treatment of heart failure, known as AAV1.SERCA2a. This vector-based therapy enables the precise delivery of therapeutics to damaged heart tissue and introduces a new realm of treatment modalities for advanced heart failure patients. The team is also exploring the use of novel gene-therapy vectors to target various forms of heart failure, ventricular arrhythmias, pulmonary hypertension, and myocardial infarction.

The laboratory has continued to target calcium cycling proteins in the heart. Recently, researchers have been successful in delivering the constitutively active form of protein phosphatase 1 inhibitor (I-1) directly into damaged heart cells. The team used newly developed recombinant adeno-associated viruses, which are nonpathogenic viruses naturally existing in the human body and are pathogenically safe while having a very low immune-response profile. Dr. Hajjar is scientific cofounder of the biotechnology company NanoCor Therapeutics, which in April 2016 won new investigational drug approval from the U.S. Food and Drug Administration for Carfostin™. That gene therapy, a one-time treatment delivered via the femoral artery into the coronary arteries, will shortly start in a multicenter phase 1 trial in patients with advanced-stage congestive heart failure.

Pulmonary Hypertension

Pulmonary arterial hypertension is a rare, rapidly progressing disease that occurs when blood pressure is too high in vessels leading from the heart to the lungs. The high pressure is caused by abnormal remodeling of the lung blood vessels that sometimes leads to failure of the right ventricle and premature death. Thickening and narrowing of pulmonary vessels is seen with all types of pulmonary hypertension



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1. In a recent gene-therapy study, the Hajjar team collected skin-cell samples from a heart failure patient who has the R14del mutation within the phospholamban (PLN) gene. The cells were transformed to become induced pluripotent stem cells (iPSCs), which were then differentiated into specialized, beating heart muscle cells called cardiomyocytes. The team used a genome-editing technique to cut out the diseased gene and replace it with a normal PLN gene, resulting in normally functioning cardiomyocytes.

and is triggered by abnormal calcium levels within the vascular cells. The sarcoplasmic reticulum calcium ATPase pump (SERCA2a) regulates intracellular calcium in vascular cells and prevents them from proliferating in the vessel wall. Dr. Hajjar's group delivered a therapeutic gene called SERCA2a in aerosol form to damaged blood vessels of the lung using an engineered adeno-associated virus (AAV). Two months after the gene delivery in a pig model of severe pulmonary hypertension, scientists performed tests to see whether the new therapeutic genes were present and functioning in the vessels of the animals' lungs and whether the transfer was producing the desired effects. When they examined the animals, they found that heart and lung function had improved and abnormal cellular changes causing pulmonary arterial hypertension were reduced.

Targeting Cardiac Fibrosis

CCN5, a matricellular protein, has been found to reverse established cardiac fibrosis in heart failure models. Cardiac fibrosis occurs when healthy cardiac cells are replaced with fibrous connective tissue, causing scarring and a stiffer and less compliant cardiac muscle. It is found to be an independent predictor for the progression of heart failure. While there currently are no effective cardiac fibrosis therapies available, it is considered a valid target for treatment. Dr. Hajjar and his team, having already established that CCN5 is significantly lower in the myocardium of patients with severe heart failure, examined whether CCN5 can reverse cardiac fibrosis in experimental models. They induced extensive cardiac fibrosis in models of heart failure, and then proceeded to transfer CCN5 to the hearts. Eight weeks later, the team examined the cellular and molecular effects. The results revealed that CCN5 had reversed cardiac fibrosis in the models. Researchers used trichrome staining and analysis of myofibroblast contents before and after CCN5 gene transfer to clearly show the reversal. The therapeutic efficacy of CCN5 continues to be investigated in preclinical models of heart failure with extensive fibrosis.

Gene Editing in Inherited Cardiomyopathies

Gene therapy can clip out genetic material linked to heart failure and replace it with the normal gene in human cardiac cells. Genetic mutations are major culprits in the weakening heart muscle seen in patients with heart failure. A number of inherited gene mutations have been associated with cardiomyopathies, including mutations in the phospholamban (PLN) gene, which is a critical regulator of healthy cardiac cell function and its calcium cycling. The R14del mutation within the PLN gene has been identified in a number of families with genetic heart failure. The mutation is linked to dilated heart muscle, dysfunctional heart muscle contraction, dangerous arrhythmias, and the development of heart failure by middle age.

In a recent study, Dr. Hajjar's team collected skin cell samples from a heart failure patient who has the R14del mutation. The skin cells from the patient were then transformed in the laboratory to become induced pluripotent stem cells (iPSCs). These stem cells, which carry the genetics of the heart failure patient, were then differentiated from the skin cells into specialized heart muscle cells called cardiomyocytes (iPSC-CMs), which also carry the patient's genetic history. To correct the gene mutation in cardiomyocytes, researchers successfully used two novel methods. First, they used specifically designed transcription activator-like effector nucleases called TALENs to target and eliminate the presence of R14del-associated disease in cardiac cells. This genome-engineering technique cut out the diseased gene and replaced it with a normal PLN gene, resulting in normally functioning cardiomyocytes. Dr. Hajjar's team used an adeno-associated viral-vector gene-therapy approach, with the harmful part of a virus removed, to safely target the inside of cardiac cells, knock down the abnormal PLN gene within them, and simultaneously express the normal PLN gene, successfully reversing disease. This gene-therapy approach also corrected the functional abnormalities of the cardiac cells. These offer potential strategies to target and interrupt the disease-causing path of the mutation associated with cardiomyopathies and heart failure. Similar methods are being used for cardiomyopathies caused by Duchenne muscular dystrophy, Friedreich's ataxia, and amyloidosis.

Funding: NIH P50 HL11232 4, R01 HL119046, R01 HL117505, R01 HL128099, R01 HL128072, R01 HL129814, R01 HL105826, R01 HL131404, R01 HL113497, T32 HL007824, Transatlantic Fondation Leducq grant, and an AHA NCRP Winter 2014 Center Strategically Focused Prevention Research Network award.

Multiple laboratories at CVRC are pursuing translational studies at the forefront of cardiovascular discoveries:

- The Cardiac Bioelectricity Laboratory, led by **Fadi G. Akar, PhD,** focuses on elucidating mechanistic links between altered metabolic, mechanical, electrical, and structural properties that promote cardiac disease progression and regression, and on identifying novel targets for treating electrical dysfunction. Funding: NIH R01 HL083156, R21 AG054211, R01 HL113497, and R01 HL113499.

- The **Charles Bridges, MD, ScD,** laboratory is a pioneer in the emerging science of enhancing vector-mediated gene delivery to the heart. The laboratory's vision is to develop innovative medical device, biomaterial, and evaluation systems to improve cardiac gene transfer. Funding: NIH R01 HL083078.

- **Kevin D. Costa, PhD,** leads a laboratory that studies multiscale cardiovascular mechanobiology from subcellular to organ levels, using experimental and computational techniques including tissue engineering, atomic force microscopy, finite element modeling, and 3D bioprinting. Dr. Costa is accelerating translational aspects of this research, particularly in the area of high-fidelity testing, to understand and improve gene-, molecular-, and cell-based therapies for cardiovascular disease. Funding: NIH R01 HL115195.

- **Chiara Giannarelli, MD, PhD,** leads a laboratory that uses new technologies and innovative systems biology approaches to investigate the role of chronic inflammation in atherosclerotic cardiovascular disease. Her research team is using innovative high-dimensional technologies, like time-of-flight mass cytometry (CyTOF) and RNA sequencing, for unbiased analysis of single-cell variation and functional activation of inflammatory cells in the blood and atherosclerotic tissue of cardiovascular patients. Funding: NIH K23 HL111339, R03 HL135289, NIH-NCATS R21 TR001739, and a Multidisciplinary Research Development Initiative award

from the Department of Medicine of the Icahn School of Medicine at Mount Sinai.

- The Cardiovascular Translational Laboratory is led by **Dr. Kiyotake Ishikawa, MD,** and its main goals are translating basic findings toward clinical applications, establishing novel gene- and cell-therapy delivery methods for improving therapeutic efficacy, elucidating the physiological and molecular mechanisms involved in cardiovascular diseases, and applying state-of-art imaging techniques to diagnose cardiac pathology.

- **Chang Won Kho, PhD,** leads a laboratory that focuses on identifying and characterizing novel molecular pathways with relevance to human disease. An area of particular interest is the role of post-translational modification of key proteins involved in cardiac dysfunction. Funding: NIH R00 HL116645.

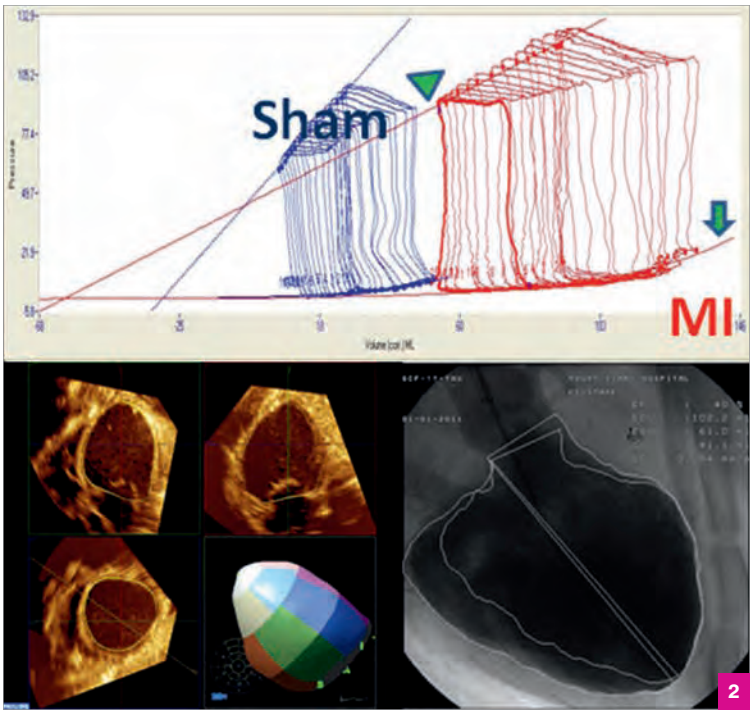
- The laboratory of **Jason D. Kovacic, MD, PhD,** has a three-part mission: to identify areas of critical unmet clinical need and major cardiovascular research questions; to engage, pursue, and dissect these issues; and to translate this knowledge back to the clinic. Funding: NIH K08 HL111330, R01 HL130423, and a Transatlantic Fondation Leducq grant.

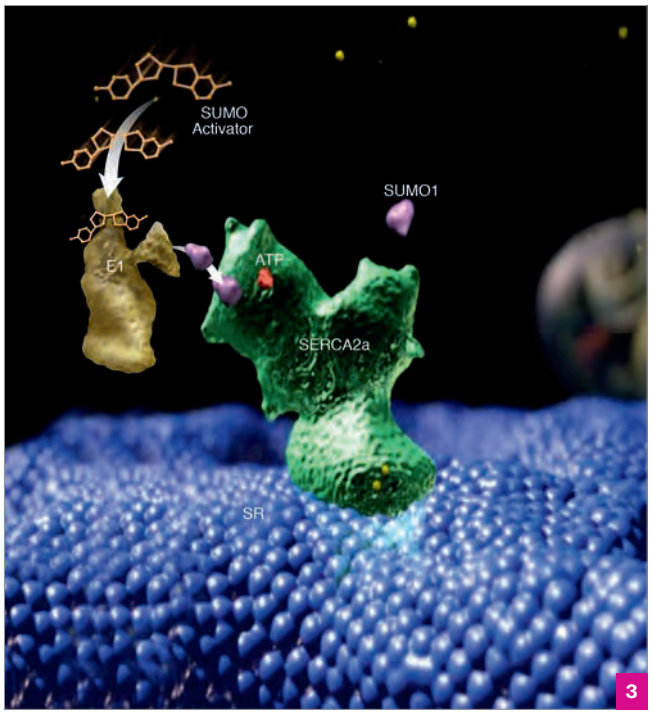
- The laboratory led by **Djamel Lebeche, PhD,** focuses on the elucidation of the genetic and cellular mechanisms underlying the pathophysiology of diabetic cardiomyopathy and the role of insulin resistance and cardiometabolism dysregulation in contractile failure. Funding: NIH R56 DK100624, DK020541, and R01 HL12981.

- **Susmita Sahoo, PhD,** conducts preclinical, translational, and basic research, investigating exosomes and epitranscriptomic mechanisms in cardiac dysfunction. Dr. Sahoo's laboratory was the first to study stem cell–derived bionanovesicles called exosomes in miRNA-mediated microcommunications for cardiac repair and regeneration. Funding: NIH R01 HL124187 and an AHA Scientific Development Grant.

- **Thomas Weber, PhD,** leads a laboratory that studies the biology of AAV–mediated gene therapy, which is a novel therapeutic platform to treat intractable cardiac disorders. Funding: DOD OC150282, NIH R01 HL131404, and a Transatlantic Fondation Leducq grant.

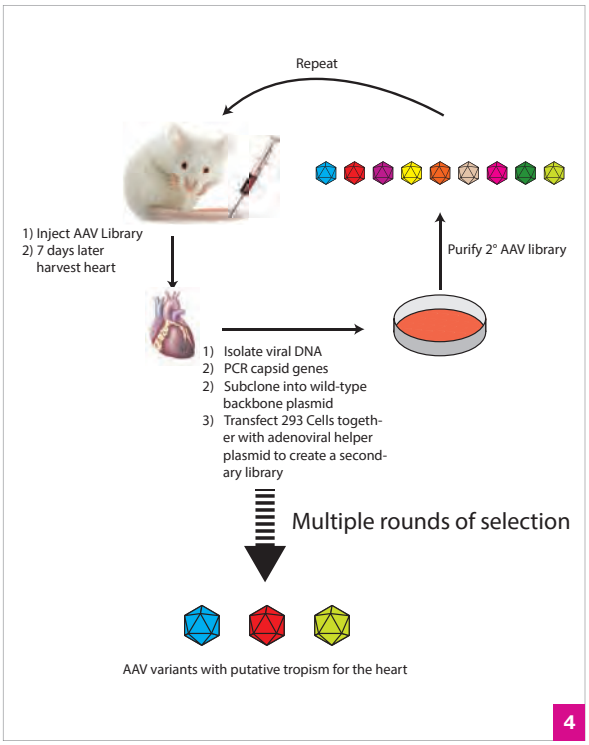
- The laboratory led by **Lior Zangi, PhD,** focuses on induction of cardiac regeneration after myocardial infarction using a gene-therapy approach with modified mRNA (modRNA). ModRNA is a novel in vivo gene-delivery method that allows high gene expression in a variety of organs, including the heart. ■





2. The Cardiovascular Translational Laboratory uses imaging techniques on large-animal models of heart failure to help translate promising research findings toward clinical application. Clockwise from top: A pressure-volume loop image of a normal pig's heart and one with a myocardial infarction; a left ventriculogram; and 3D echocardiography.

3. The Kho Laboratory demonstrated that small ubiquitin-related modifier type 1 (SUMO-1)–mediated regulation is a critical post-translational modification that positively regulates the function of a critical intracellular pump, SERCA2a. This has led to the development of a novel activator of SERCA2a SUMOylation, which is being tested in preclinical models.



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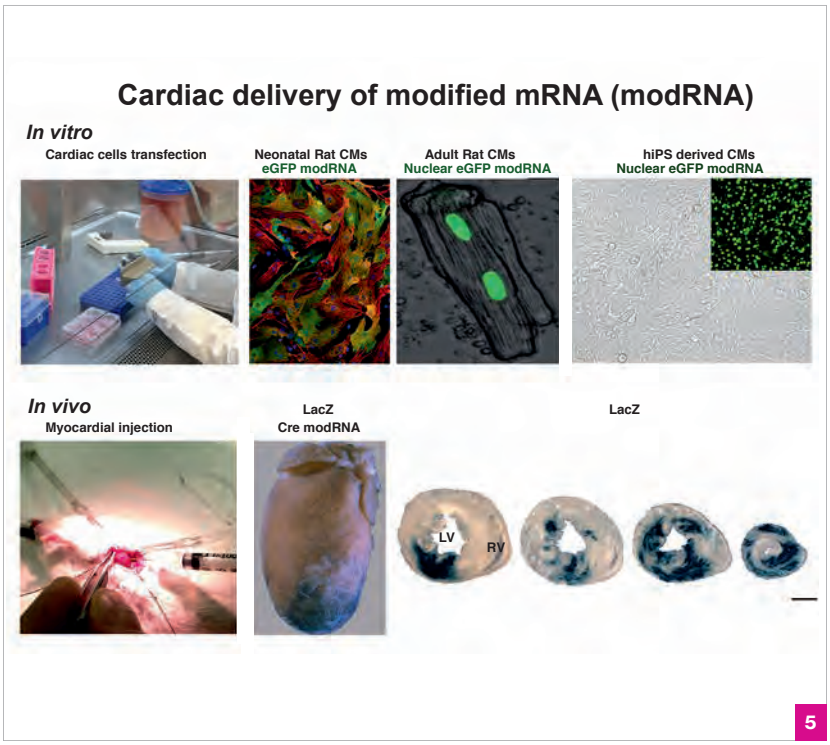

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Selected Publications

Karakikes I, Stillitano F, Nonnenmacher M, Tzimas C, Sanoudou D, Termglinchan V, Kong CW, Rushing S, Hansen J, Ceholski D, Kolokathis F, Kremastinos D, Katoulis A, Ren L, Cohen N, Gho JM, Tsiapras D, Vink A, Wu JC, Asselbergs FW, Li RA, Hulot JS, Kranias EG, Hajjar RJ. Correction of human phospholamban R14del mutation associated with cardiomyopathy using targeted nucleases and combination therapy. Nat Commun 2015;6:6955.

Kho C, Lee A, Jeong D, Oh JG, Gorski PA, Fish K, Sanchez R, DeVita RJ, Christensen G, Dahl R, Hajjar RJ. Small-molecule activation of SERCA2a SUMOylation for the treatment of heart failure. Nat Commun 2015;6:7229.

Tilemann L, Lee A, Ishikawa K, Aguero J, Rapti K, Santos-Gallego C, Kohlbrenner E, Fish KM, Kho C, Hajjar RJ. SUMO-1 gene transfer improves cardiac function in a large-animal model of heart failure. Sci Transl Med 2013;5(211):211ra159.

Kho C, Lee A, Jeong D, Oh JG, Chaanine AH, Kizana E, Park WJ, Hajjar RJ. SUMO1-dependent modulation of SERCA2a in heart failure. Nature 2011;477(7366):601–5.

Jessup M, Greenberg B, Mancini D, Cappola T, Pauly DF, Jaski B, Yaroshinsky A, Zsebo KM, Dittrich H, Hajjar RJ. Calcium upregulation by percutaneous administration of gene therapy in cardiac disease (CUPID): a phase 2 trial of intracoronary gene therapy of sarcoplasmic reticulum Ca2+-ATPase in patients with advanced heart failure. Circulation 2011;124(3):304–13.

4. Adeno-associated virus (AAV)–mediated gene therapy is a novel therapeutic platform to treat intractable cardiac disorders that has shown success in animals, but not yet humans. The Weber Laboratory is seeking to isolate AAV variants with a greater resistance to neutralizing antibodies found in the human population. In this effort, researchers are pursuing directed evolution, putting libraries of AAVs through several selection steps to isolate the variants with the highest therapeutic potential.

5. The Zangi Laboratory focuses on induction of cardiac regeneration after myocardial infarction, using a gene-therapy approach with modified mRNA (modRNA). Modified RNA is a recently developed platform for the safe and effective delivery of genes. The laboratory has been able to establish modRNA gene delivery in cardiac cells (upper panel) and in vivo (lower panel) in animal models. It is expected that this technology to introduce genes in the cardiovascular system will be tested in humans in the next few years.

Team

In alphabetic order: Fadi G. Akar, PhD, *Associate Professor of Medicine (Cardiology)*; **Marine Cacheux, PhD**; **Kyle Chamberlain, PhD**; **Jiqiu Chen, MD,** *Assistant Professor of Medicine (Cardiology)*; **Kevin Costa, PhD,** *Director of Cardiovascular Cell and Tissue Engineering*; **Anthony Fargnoli, PhD,** *Assistant Professor of Medicine (Cardiology)*; **Ahmed Farhat**; **Chiara Giannarelli, MD, PhD,** *Assistant Professor of Medicine, (Cardiology)*; **Yoav Hadas, PhD**; **Roger J. Hajjar, MD,** *Director, Cardiovascular Research Center*; **Jun Hu, PhD**; **Kiyotake Ishikawa, PhD,** *Assistant Professor of Medicine (Cardiology)*; **Dongtak Jeong, MD**; **Michael Katz, PhD,** *Assistant Professor of Medicine (Cardiology)*; **Okkil Kim, MS**; **Jason Kovacic, MD, PhD,** *Associate Director of the Interventional Structural Heart Disease Program*; **Djamel Lebeche, PhD,** *Associate Professor of Medicine (Cardiology)*; **Philyoung Lee, PhD**; **Lauren Leonardson**; **Lifan Liang, MD**; **Yaxuan Liang, PhD**; **Ajit Magadum, PhD**; **Adriano Martins, PhD**; **Prabhu Mathiyalagan, PhD**; **Joshua Mayourian, MD, PhD**; **Jaegyun Oh, PhD**; **Jalish Riyad, MA**; **David Sachs, MS,** *Assistant Professor of Genetics and Genomic Sciences*; **Susmita Sahoo, PhD,** *Assistant Professor of Medicine (Cardiology)*; **Yassine Sassi, PhD**; **Rajvir Singh, PhD**; **Francesca Stillitano, PhD**; **Benjamin Strauss**; **Nishat Sultana**; **PhD**; **Maria Trivieri, MD, PhD**; **Luca Troncone, PhD**; **Irene Turnbull, PhD**; **Shin Watanabe, MD**; **Thomas Weber, PhD,** *Associate Professor of Medicine, Cardiology*; **Elias Youssef**; **Lior Zangi, PhD,** *Assistant Professor of Medicine (Cardiology)*; and **Shihong Zhang.**

Exploring the Molecular Genetics of Pediatric Cardiovascular Disease

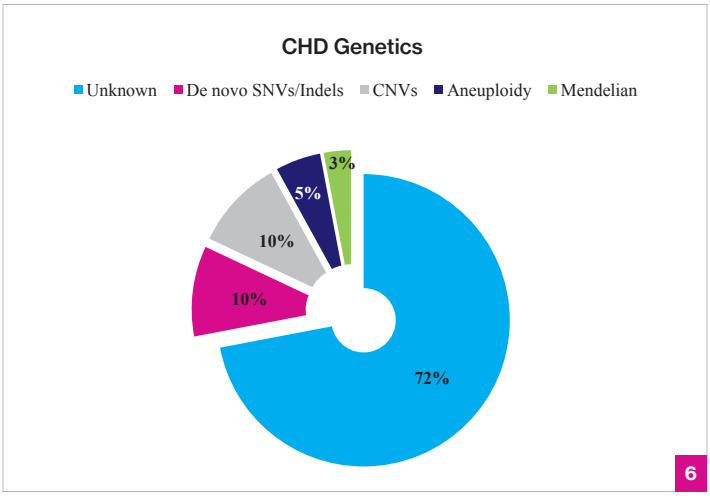
Bruce D. Gelb, MD, *Gogel Family Chair and Director of The Mindich Child Health and Development Institute, and Professor of Pediatrics and of Genetics and Genomic Sciences, Icahn School of Medicine at Mount Sinai*

Researchers at the Center for Molecular Cardiology at the Icahn School of Medicine at Mount Sinai are interested in understanding the genetic pathogenesis of cardiovascular diseases of childhood. The Center is led by Bruce D. Gelb, MD, Gogel Family Chair and Director of The Mindich Child Health and Development Institute, and Professor of Pediatrics and of Genetics and Genomic Sciences. The Center's primary focus is congenital heart disease (CHD), which is principally a complex genetic trait but can be Mendelian in some cases. The molecular genetic revolution generally and the recent advances in DNA sequencing technology in particular have enabled discovery of the specific genetic variations that cause CHD.

Dr. Gelb's research group is pursuing a broad range of studies of Noonan syndrome and related disorders, now called the RASopathies because they all arise from mutations in RAS/MAP kinase signal transduction. Currently, they are modeling aspects of cardiac defects in RASopathies using human-induced pluripotent stem cells (iPSCs), focusing primarily on understanding the pathogenesis of hypertrophic cardiomyopathy. In addition, researchers have developed fruit fly models of Noonan syndrome, which they are using to screen and then develop drug therapies for the RASopathies.

Through the Pediatric Cardiac Genomics Consortium, funded by the National Heart, Lung, and Blood Institute, the Gelb group is undertaking a wide variety of genomic studies to discover mutations causing congenital heart disease. The Consortium has established that 10 percent of CHD is attributable to de novo mutations that alter genes important for cardiovascular development, and that altered histone biology has a key role in CHD pathogenesis. Currently, the Consortium is expanding its activities with the addition of exome sequencing, whole genome sequencing, and modeling of disease using iPSCs. In addition, a clinical study examining the role of de novo mutations in neurodevelopmental outcomes is just beginning.

Dr. Gelb's work is supported by NIH R01 HL071207, R01 HL113499, UM1 HL098123, and U54 OD020353. ■



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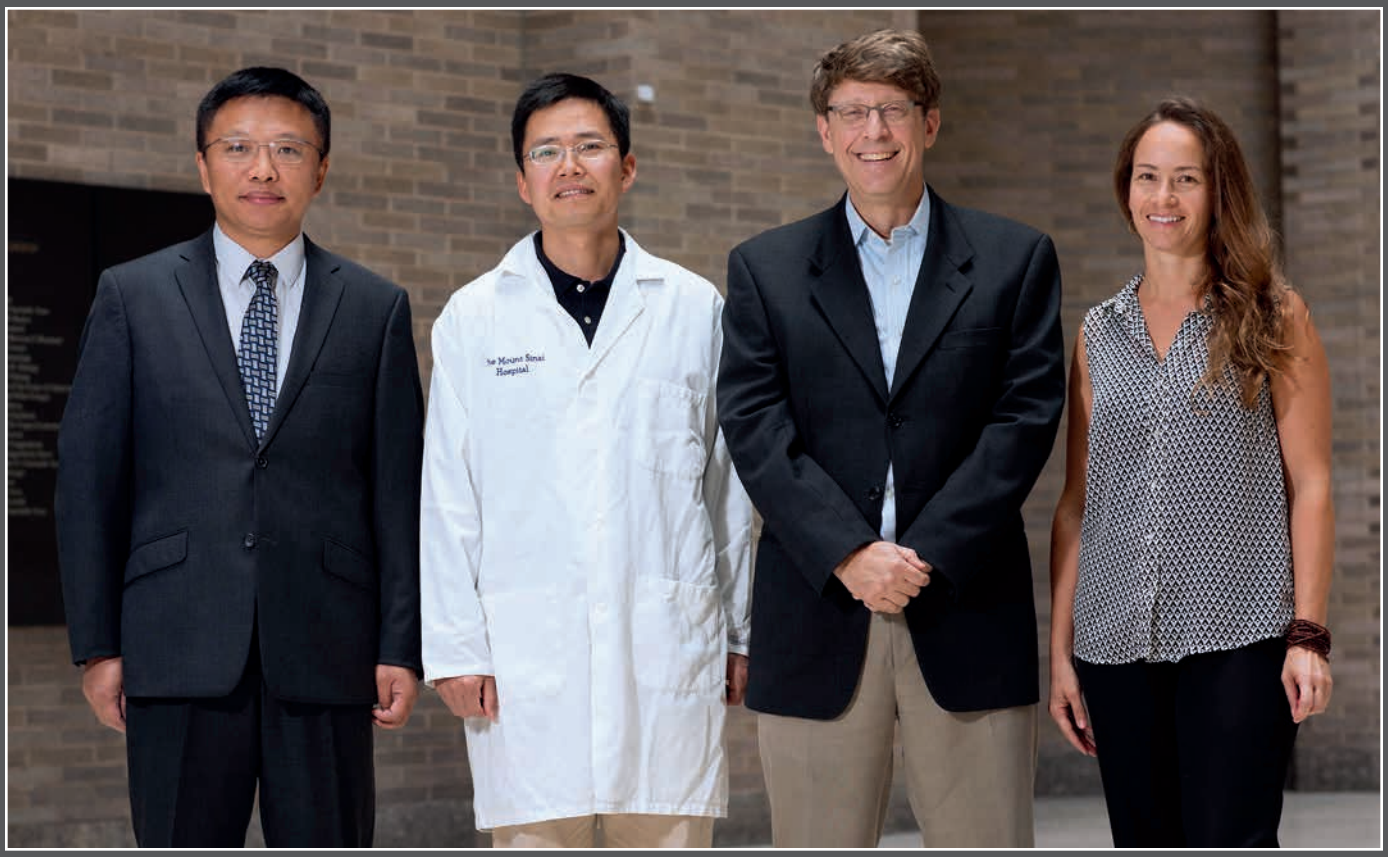
About Dr. Gelb

Bruce D. Gelb, MD, is the Gogel Family Chair and Director of The Mindich Child Health and Development Institute, Director of the Center for Molecular Cardiology, and Professor of Pediatrics and of Genetics and Genomic Sciences, Icahn School of Medicine at Mount Sinai. In his quest to discover what causes congenital heart disease, Dr. Gelb has developed an extensive program in genomics and gene investigation, focusing on traits associated with heart malformations. An expert in Noonan syndrome, Dr. Gelb has studied the genetic origins of the disease to understand its pathogenesis. In addition to conducting his research, Dr. Gelb directs the Cardiovascular Genetics Program at Mount Sinai. He is also the President of the International Pediatric Research Foundation and a council member of the American Pediatric Society.

6. Congenital heart disease (CHD) is a complex genetic trait, with the cause unknown in 72 percent of cases. A consortium including the Gelb group has established that 10 percent of CHD is attributable to de novo mutations that alter genes important to cardiovascular development.



Team

From left: Chenleng Cai, PhD, *Associate Professor of Developmental and Regenerative Biology*; **Yong Zhao, MD, PhD,** *Assistant Professor of Genetics and Genomic Sciences*; **Bruce D. Gelb, MD,** *Director, The Mindich Child Health and Development Institute*; **Nicole Dubois, PhD,** *Assistant Professor of Developmental and Regenerative Biology.*

CLINICAL DATA MANAGEMENT

InCHOIR Strengthens the Evidence Base For Cardiovascular Diagnostics and Therapies

Annetine C. Gelijns, PhD, *Edmond A. Guggenheim Professor and Chair of Population Health Science and Policy at the Icahn School of Medicine at Mount Sinai*

By any standard, cardiovascular medicine has been a dynamic field of medicine. The introduction of major diagnostic and therapeutic innovations, and ongoing incremental change in such areas as coronary artery bypass grafting (CABG), percutaneous cardiac interventions, novel drugs, behavioral interventions to change lifestyles, cardiac valve replacement and repair, myocardial protection, mechanical circulatory support, aortic reconstruction, and the treatment of arrhythmias, have extended survival and improved quality of life for many patients suffering from cardiac disease. This rapid pace of innovation requires a rigorous infrastructure for clinical evaluation of new treatments. However, this infrastructure has been typically not very robust, and for many interventions the evidence base is weak.

The mission of the International Center for Health Outcomes and Innovation Research (InCHOIR) is to strengthen the evidence base for cardiovascular diagnostics and therapies by conducting randomized comparative-effectiveness trials and clinical trials of novel therapeutics, including cell-based and gene-based therapies. InCHOIR is led by Annetine C. Gelijns, PhD, Edmond A. Guggenheim Professor of Population Health Science and Policy at the Icahn School of Medicine at Mount Sinai, along with Co-Director Alan J. Moskowitz, MD, also a Professor of Population Health Science and Policy at the medical school. The Center comprises an interdisciplinary faculty with expertise in the novel design of trials, clinical coordination, regulatory issues and management, endpoint and event adjudication, electronic data-collection systems, novel apps, statistical analysis, health economics, and quality-of-life assessment. Over time, InCHOIR has developed a portfolio of trials that evaluate clinically meaningful questions and address important public-health issues.

The trials that InCHOIR has conducted over the past 15 years—beginning with REMATCH, which established left ventricular assist devices as destination therapy for advanced heart failure—have shaped treatment paradigms. This trial, published in *The New England Journal of Medicine*, led to U.S. Food and Drug Administration approval of this new therapy and coverage approval by Medicare and private payers.

InCHOIR currently serves as the Coordinating Center for the Cardiothoracic Surgical Trials Network funded by the National Institutes of Health, and our research on surgical treatment for patients with ischemic mitral valve disease, surgical ablation for atrial fibrillation, and management of postoperative atrial fibrillation (all published in *The New England Journal of Medicine*) is changing both clinical practice and the guidelines adopted by professional societies. InCHOIR plans to expand its collaborative research agenda with Mount Sinai's Interventional Cardiology team and

About Dr. Gelijns

Annetine C. Gelijns, PhD, is the Edmond A. Guggenheim Professor of Population Health Science and Policy at the Icahn School of Medicine at Mount Sinai, Chair of the Department of Population Health Science and Policy, and Co-Director of the International Center for Health Outcomes and Innovation Research (InCHOIR) at Mount Sinai. Her recent work has focused on the design, execution, and policy implications of clinical trials of novel surgical procedures, drugs, and implantable devices. She directed the data coordinating center for the landmark REMATCH trial, which established the survival and quality-of-life benefit of implanted mechanical circulatory support devices for patients with advanced heart failure. Dr. Gelijns, an international leader in her field, has conducted research that provides critical insight into the forces that drive the rate and direction of technological change in medicine.

other investigators over the next five years as follows:

Expand Translational Clinical Trial Capabilities

InCHOIR is conducting early-phase studies, in collaboration with Roger Hajjar, MD, in the area of gene therapy and mesenchymal precursor stem cells as well as in novel mechanical circulatory support devices with Sean P. Pinney, MD, Anuradha Lala, MD, and Donna M. Mancini, MD.

Expand Pragmatic Trials at the Point of Clinical Care

We have been funded by the National Heart, Lung, and Blood Institute for a pragmatic trial of hybrid coronary revascularization (PCI plus CABG), which utilizes data from, among other sources, the clinical registries of the Society of Thoracic Surgeons and the American College of Cardiology. Using a similar data-collection process, we have, in collaboration with Mount Sinai's Office of Interventional Cardiology Trials, submitted a proposal to evaluate the addition of clopidogrel to the standard antithrombotic regimen after transcatheter aortic valve replacement. In our clinical trials, we attempt to combine clinical data with those from biobanks to conduct genomic and biomarker analyses. Our efforts in this realm are leading to innovative trials that predominantly use data from the electronic health record and that can, thereby, drastically improve the efficiency of clinical trials.

Develop Novel Patient-Centered Data-Collection Tools

InCHOIR has developed an innovative electronic data-capture system that incorporates apps to screen and randomize patients. We plan to expand our expertise in collecting data from patients using novel apps to monitor aspects of health status, like weight, exercise, and sleep, and obtain data on quality of life and patients' frailty. These data will complement those derived from clinical encounters and further reduce the costs of conducting clinical trials.

Implementation Science and Health Care Disparities

The results of trials often make a case for changing practice, but we know that there is typically a 15-year lag between trial publications and adoption in practice. One area of future research to reduce this lag is to improve the creation of tools to help physicians and patients evaluate risks and share in decision making. We have developed a group that is creating such tools.

Another important shortcoming in the current health care system is the underrepresentation of minorities, and we are building strategies and approaches to enhance equity in the delivery of cardiovascular care. We have conducted trials to improve the management of heart failure among African American and Latino residents of Harlem, for example, and in collaboration with Valentin Fuster, MD, PhD, and Rajesh Vedanthan, MD, are collaborating on research to reduce disparities in health outcomes globally.

Quality-Improvement Studies

Quality improvement is an important focus for InCHOIR. Reducing infections is a case in point. Hospital-acquired infections represent the predominant noncardiac complication after heart surgery, and they are associated with substantial morbidity, higher mortality, prolonged hospitalizations, and increased rates of readmissions. While prior studies have examined the relationship between patient characteristics, like comorbid conditions, and hospital-acquired infections after cardiac surgery, the literature has not sufficiently examined the relationship between treatment practices, such as management of lines and ventilators, and postoperative infection risk. Knowledge about this relationship is critical to developing interventions to avert infections. We recently enrolled more than 5,200 patients in a prospective cohort study that assesses major infections (such as deep surgical site infection, endocarditis, mediastinitis, and pneumonia) and minor infections (such as superficial surgical site infections) after cardiac surgery. This study has identified management practices that put patients at high risk for infections and has provided insights to help guide the development of more effective strategies for reducing these debilitating and costly complications. ■

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Building an infrastructure for evaluating new treatments.

1. Annetine C. Gelijns, MD, Director of InCHOIR, and Alan J. Moskowitz, MD, Co-Director.

Center of Interventional Cardiovascular Research and Clinical Trials Uses Informatics to Study and Enhance Care

Roxana Mehran, MD, FACC, *Professor of Medicine (Cardiology) and Population Health and Policy at the Icahn School of Medicine at Mount Sinai*

The central mission of the Center of Interventional Cardiovascular Research and Clinical Trials is to improve outcomes and enhance the quality of health care delivered to the millions of patients suffering from cardiovascular diseases. To achieve these goals, our Center is involved in research efforts that span multicenter observational registries and large-scale randomized trials, quality initiatives to introduce treatment protocols and standardize care pathways, and development of novel applications and informatics resources to conduct pragmatic and innovative clinical studies. We have developed very productive collaborations both within and outside the Mount Sinai Health System with partners that share common goals and provide a natural synergy with our mission.

The Center is led by Roxana Mehran, MD, FACC, Professor of Medicine (Cardiology) and Population Health and Policy at the Icahn School of Medicine at Mount Sinai (ISMMS). Another leader in this effort is Usman Baber, MD, Assistant Professor of Medicine (Cardiology) and Director of Clinical Biometrics at The Zena and Michael A. Wiener Cardiovascular Institute at ISMMS.

Research

Research led by the Center includes both registry-based observational studies that have provided valuable insights on patterns of care, outcomes, and determinants of clinical decision making and formal experimental studies evaluating various treatment strategies. Findings from the PARIS registry study, for example, introduced a novel approach to defining, quantifying, and analyzing dual antiplatelet therapy in patients treated with coronary stents. These findings are now being embedded in a formal adherence classification protocol by the Academic Research Consortium. The Center also serves as the sole sponsor of the global randomized TWILIGHT trial, which is evaluating antiplatelet strategies among high-risk patients after PCI. In the trial, the first of its kind, after three months of dual treatment with the antiplatelet medication ticagrelor plus aspirin, patients stop taking aspirin with the goal of reducing adverse events and bleeding.

Quality

Demonstrating and quantifying high-quality care is a major and growing focus for national and state regulatory bodies and for third-party payers. This is increasingly predicated on participation and submission of data to national registries, which is typically a labor-intensive task. At Mount Sinai, however, the Center has developed an electronic application that harvests data from our existing IT resources and automatically submits PCI data to the National Cardiovascular Data Registry. Thus, we were able to join the registry without hiring additional personnel and also shift resources from data abstraction to data validation and follow-up evaluation. To date, our application remains unique as the only automated solution developed among the registry's participating hospitals. The Center was also involved in the development of a systemwide acute myocardial infarction (MI) protocol and in efforts to streamline care for acute MI patients with the American Heart Association's Mission: Lifeline program.

Electronic Applications

Leveraging informatics resources, developing mobile data solutions, and partnering with national registries are key components of efforts by the Center to enhance the efficiency and lower the costs of conducting modern-day clinical research. In the AVIATOR-2 registry study, for example, we developed a mobile-application-based survey tool that can

Developing novel applications and data resources for clinical studies.

About Dr. Mehran

Roxana Mehran, MD, FACC, FACP, FCCP, FESC, FAHA, FSCAI, is Professor of Medicine and Director of Interventional Cardiovascular Research and Clinical Trials at the Zena and Michael A. Wiener Cardiovascular Institute in the Icahn School of Medicine at Mount Sinai. Dr. Mehran is internationally recognized for her work as a clinical trial specialist with complex data analyses and outcomes research in the field of interventional cardiology and for her experience and expertise in working with regulatory agencies to conduct clinical trials. Her research interests expand from mechanisms of restenosis to treatment and prevention of acute kidney injury in cardiac patients and include advancing treatments for acute coronary syndromes and acute myocardial infarction.

be deployed at the point of care to gain insights into clinical decision making surrounding anticoagulant and antiplatelet therapy among patients with atrial fibrillation undergoing PCI. We have also worked with the Department of Population Health Science and Policy at ISMMS and with the national Annual Outcomes With Transcatheter Valve Therapy Registry to design a large-scale, pragmatic clinical trial testing antiplatelet therapies among patients undergoing transcatheter aortic valve replacement (TAVR). This study will leverage the existing infrastructure of this national registry for the purposes of identifying sites, screening patients, entering data, and performing follow-up visits. Such a pragmatic, low-cost design is increasingly advocated by the National Institutes of Health and the federal government to answer important questions with major public-health implications. ■

Selected Publications

Dangas GD, Lefevre T, Kupatt C, Tchetche D, Schafer U, Dumonteil N, Webb JG, et al. Bivalirudin versus heparin anticoagulation in transcatheter aortic valve replacement: The Randomized BRAVO-3 Trial. J Am Coll Cardiol 2015;66:2860–68.

Khera AV, Emdin CA, Drake I, Natarajan P, Bick AG, Cook NR, et al. Genetic risk, adherence to a healthy lifestyle, and coronary disease. N Engl J Med 2016;375:2349–58.

Stone GW, Sabik JF, Serruys PW, Simonton CA, Genereux P, Puskas J, et al. Everolimus-eluting stents or bypass surgery for left main coronary artery disease. N Engl J Med 2016;375:2223–35.

Levine GN, Bates ER, Bittl JA, Brindis RG, Fihn SD, Fleisher LA, et al. 2016 ACC/AHA guideline focused update on duration of dual antiplatelet therapy in patients with coronary artery disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2016;68:1082–115.

Gibson CM, Mehran R, Bode C, Halperin J, Verheugt FW, Wildgoose P, et al. Prevention of bleeding in patients with atrial fibrillation undergoing PCI. N Engl J Med 2016;375(25):2423–34.

Yu J, Baber U, Mastoris I, Dangas G, Sartori S, Steg PG, et al. Sex-based differences in cessation of dual-antiplatelet therapy following percutaneous coronary intervention with stents. JACC Cardiovasc Interv 2016;9:1461–9.

Center for Medical Devices and Cardiovascular Surgery Outcomes Database

Julie Swain, MD, *Vice Chair for Clinical Performance for the Mount Sinai Health System, and Professor of Cardiovascular Surgery and Director of Clinical Research in the Department of Cardiovascular Surgery at the Icahn School of Medicine at Mount Sinai*

The Department of Cardiovascular Surgery at Mount Sinai Heart has created an innovative new Center for Medical Devices (CMeD) to advance the field of cardiovascular medicine and accelerate the delivery of promising medical-device technology to cardiac patients. The mission of CMeD is to provide medical-device companies expert advice in all aspects of clinical-trial design, device testing, and regulatory-approval requirements. The Center is led by Julie Swain, MD, Vice Chair for Clinical Performance and Director of Clinical Research in the Department of Cardiovascular Surgery at the Icahn School of Medicine at Mount Sinai. Dr. Swain is a cardiovascular surgeon who is internationally recognized as an expert in clinical trial design.

Given our academic medical center's expertise in cardiovascular medicine and cardiac

About Dr. Swain

Julie Swain, MD, is Professor and Vice Chair for Clinical Performance in the Department of Cardiovascular Surgery for the Mount Sinai Health System and Director of the Center for Medical Devices at Mount Sinai Heart. In addition, she serves as Director of Clinical Research in the Department of Cardiovascular Surgery. Dr. Swain has been an academic cardiothoracic and vascular surgeon for more than 21 years, has designed and conducted clinical research trials, and has led cardiovascular physiology basic science laboratories. She served as an advisor to the U.S. Food and Drug Administration (FDA) for more than 20 years, including eight years as a member and Chair of the FDA's Cardiovascular Advisory Panel. She is currently a member of the Medicare Evidence Development and Coverage Advisory Committee of the Centers for Medicare & Medicaid Services.

surgery, CMeD is well-positioned to advance the evaluation of transcatheter structural heart devices. The Center is integrated with the Department of Cardiovascular Surgery, which maintains a robust clinical-research program and performs a high volume of cardiovascular procedures, with the aim of bringing the newest medical devices, drugs, and interventions to our patients. The Department participates in and leads international cardiac surgery trials. For example, over the past decade we have led trials in transcatheter and surgically implanted heart valves and are participating in clinical studies on new drugs, aortic grafts, blood-clotting agents, heart preservation systems, and ventricular assist devices.

Working with the Mount Sinai Hospital System's Data Analytics group, Dr. Swain created the Cardiovascular Outcomes Database to collect, analyze, and report a large amount of data from cardiovascular operations in the Mount Sinai Health System. This powerful database of more than 8,500 patients is utilized in our CMeD clinical-research program and provides real-time information to surgeons about their cardiac surgery results in order for them to assess their techniques, evaluate care, and improve the service they give to patients. This database allows departmental and hospital leadership to assess quality and improve patient care in a cost-efficient way. All patients are enrolled in several national and state databases so that we can compare our results among the hospitals in the Mount Sinai System, the hospitals in New York State, and all hospitals in the nation. With the development of this database, the Department of Cardiovascular Surgery continues to be a leader in assessing and continually improving the quality of care for our patients. ■

Team

From left: Vanessa Coulibaly, MS, *Research Coordinator*; **Roberto Galao-Malo, NP, MPH,** *Quality Coordinator*; **Julie Swain, MD**, *Director*; **Bernadette Flaim,** *Administrator*; **Michael Fusilero, MD,** *Lead Research Coordinator*; **Jerome Tonog, MD**, *Research Coordinator.*

THE EXTENDED CARDIAC CARE TEAM

Cardiac Nursing

Led by Beth Oliver, DNP, RN, Senior Vice President of Cardiac Services for the Mount Sinai Health System and a global leader in cardiac nursing, the nurses and nurse practitioners at Mount Sinai Heart are at the forefront of the delivery of cardiovascular care in every service area, in both the inpatient and outpatient settings.

Mount Sinai Heart's 350 highly experienced nurses and 70 nurse practitioners care for more than 50,000 heart patients a year. The Mount Sinai Hospital has received Magnet designation in three consecutive cycles from the American Nurses Credentialing Center (2004–08, 2009–13, and 2014–18), a prestigious honor achieved by only six percent of hospitals in the United States. This gold-standard designation in nursing care represents the highest quality of comprehensive patient care and is associated with better patient outcomes and satisfaction, greater registered nurse job satisfaction and engagement, lower staff turnover, and meeting or exceeding national benchmarks for quality and safety in patient care.

Almost all of Mount Sinai Heart's nurses hold a bachelor's degree in nursing, well above the national average of approximately 50 percent. They maintain an environment that supports professional development, interdisciplinary collaboration, and scholarship, enabling Mount Sinai to provide the highest-quality, evidence-based care.

The nurses and nurse practitioners at Mount Sinai Heart have specialized knowledge and skills in the care of arrhythmia and heart rhythm disorders, including electrocardiogram interpretation, sedation and analgesia, and patient education. A one-to-four nurse-patient ratio on units caring for inpatients with coronary artery disease allows each nurse to monitor patients closely and frequently.

In the field of heart failure and transplantation, Mount Sinai Heart nurses have advanced education and training in the skills required to provide comprehensive care for advanced heart failure patients, including those with heart transplantation or circulatory assist devices such as the left ventricular assist device and the Total Artificial Heart.

The nurses in the Cardiac Catheterization Laboratory are highly skilled in caring for patients using the latest and most innovative interventional cardiology procedures. Called "the backbone of the Catheterization Laboratory" by Director Samin K. Sharma, MD, they work in close collaboration with physicians and make a significant contribution to the Laboratory's outstanding safety record.

Nurses in the Cardiac Care Unit have specialized training and expertise in mechanical ventilation, advanced hemodynamic monitoring, pacemakers, intra-aortic balloon pumps, ventricular assist devices, and other critical technologies. In 2014, the Unit received the prestigious Silver Beacon Award for Excellence from the American Association of Critical Care Nurses. Only a handful of critical care units in New York State have received this honor, which recognizes nurses for a consistent and systematic approach to evidence-based care that optimizes patient outcomes. ■

Cardiothoracic Anesthesiology

The Division of Cardiothoracic Anesthesiology at The Mount Sinai Hospital, led by Menachem Weiner, MD, has a long history of excellence in clinical care and continues to expand in the clinical and research domains. The Division's 15 cardiothoracic anesthesiologists are board certified in anesthesiology, have undergone additional training, and are specifically dedicated to the perioperative care of cardiac surgical patients. As an academic department of anesthesiology, the Division's primary mission is to provide superb clinical care in an environment of uncompromising patient safety, while also striving for leadership in education and research.

Many of the Division's anesthesiologists are both clinical and academic leaders in the field, with national and international reputations. They have authored and edited definitive subspecialty textbooks, published numerous research articles and educational manuscripts in prestigious medical journals, and developed many online multimedia educational resources to help train others. Members of the Division are highly sought-after lecturers at regional, national, and international symposia and are involved with

several specialty professional societies. They serve on subspecialty boards of governance, are active members of standards and guidelines writing committees, and, for the past 35 years, have organized an annual international continuing medical education symposium about cardiothoracic surgery and anesthesia.

All of the cardiac anesthesia faculty members are board certified by the National Board of Echocardiography in perioperative transesophageal echocardiography (TEE). Mount Sinai Heart performs approximately 2,000 TEE exams each year. Surgeons and anesthesiologists using echocardiography often collaborate to help develop and guide new and evolving surgical techniques.

Advances in knowledge derived from the research of academic surgeons and anesthesiologists have made cardiac surgery and anesthesia much safer than in prior eras, and ongoing research portends continued enhancements to patient care. The primary focus of the Division's research is the study of factors that may be predictors of outcomes in patients undergoing cardiac surgical procedures. Recent projects have looked at left ventricular mass, vasoplegia, hemodynamic variability, and ventilation. Areas of active research include new uses for monitoring techniques such as 3D echocardiography and near infrared spectroscopy, medical informatics, techniques specific to pediatric and geriatric cardiac anesthesia, coagulation and hemostasis, platelet-function monitoring, and transfusion algorithms to minimize unnecessary transfusions during cardiac surgery. ■

Cardiovascular Surgical Intensive Care Unit

The Cardiovascular Surgical Intensive Care Unit at Mount Sinai Heart focuses on patients undergoing cardiac surgical procedures in a specialized 24-bed unit. The dedicated team includes 8 board-certified critical care physicians, 12 physician associates and nurse practitioners, and 90 cardiac surgery nurses, in addition to fellows, residents, physical therapists, and nutritionists who all use the latest technology to assist patients in their recovery after surgery. The unit is led by Robin Varghese, MD, Director of Cardiovascular Critical Care for the Mount Sinai Health System, and Leila Hosseinian, MD, Co-Director of The Mount Sinai Hospital Cardiovascular ICU.

The goal of the critical care team is to help patients recover rapidly after surgery. The team cares for patients undergoing a variety of procedures, from coronary bypass grafting surgery to complex valve reconstruction, cardiac transplantation, and mechanical support. This dedicated group of professionals ensures a smooth transition from the operating room to the intensive care unit, providing critical care attending-level support around the clock for patients during their recovery. Always striving to improve quality and patient satisfaction, the team's specialized critical care nurses have received Magnet recognition and are experts at caring for postoperative cardiac surgical patients.

The critical care team has contributed to making Mount Sinai's cardiac-surgery outcomes some of the best in the nation in terms of low mortality and postsurgical complications. Along with achieving these results, the team strives to constantly find ways to improve patient outcomes.

This past year the team has focused on initiatives to decrease hospital-associated infections, postoperative ventilation times, and postoperative blood transfusions. They have increased fourfold the number of patients who are extubated within six hours of arrival to the ICU to almost 40 percent of patients after coronary bypass and valve surgery. This improvement has led to better patient comfort, less postoperative sedation, and faster patient recovery after surgery. Over the past three years, the team has decreased blood transfusions by 25 percent and has implemented various best-practice measures that have decreased the incidence of hospital-acquired infections. ■

Cardiac Care Unit/Cardiovascular Intensive Care Unit

The Cardiac Care Unit, led by Umesh K. Gidwani, MD, has evolved into a cardiovascular intensive care unit (CICU) responsible for medically complex patients with acute and chronic cardiovascular disease. The CICU is staffed by cardiac intensivists who have expertise in acute cardiovascular disease and critical care medicine and provide state-of-the-art care with a multidisciplinary care team.

Empathic, responsive, patient- and family-focused care is delivered in the CICU. The unit is equipped and staffed to provide the latest in technology, including targeted temperature management (therapeutic hypothermia), catheter-directed fibrinolysis for venous thromboembolic disease, tailored inotropic therapy, and a full spectrum of options for temporary mechanical circulatory support, including extracorporeal membrane oxygenation, Impella™, and TandemHeart™ ventricular assist devices.

The unit supports multidisciplinary subspecialty teams, which provide percutaneous options for structural heart disease; management of adult congenital heart disease; therapy for severe pulmonary hypertension; ablation of refractory arrhythmias; management of advanced heart failure, heart transplantation, and cardiac devices; and complex peripheral, carotid, and coronary interventions. ■

Icahn School of Medicine at Mount Sinai

Mount Sinai Beth Israel

Mount Sinai Brooklyn

The Mount Sinai Hospital

Mount Sinai Queens

Mount Sinai St. Luke's

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New York Eye and Ear Infirmary of Mount Sinai

Mount Sinai

For you. For life.

QUICK FACTS

ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI

RANKED No. 1
AMONG PRIVATE MEDICAL SCHOOLS IN TOTAL RESEARCH DOLLARS PER PRINCIPAL INVESTIGATOR

$290 MILLION
IN TOTAL NIH FUNDING

MOUNT SINAI HEALTH SYSTEM

7,100+
PHYSICIANS

THE MOUNT SINAI HOSPITAL
RANKED No. 15
NATIONALLY BY *U.S. NEWS & WORLD REPORT*

4 MILLION
ANNUAL PATIENT VISITS

2016 DEPARTMENTAL HIGHLIGHTS

RANKED No. 8
NATIONALLY FOR CARDIOLOGY/HEART SURGERY BY *U.S. NEWS & WORLD REPORT*

25,081
CARDIAC INTERVENTION AND CARDIAC SURGERY CASES IN 2015

HONORS & AWARDS

RANKED No. 3
BY DIVERSITYINC AMONG HOSPITALS AND HEALTH SYSTEMS

RANKED No. 4
FOR DATA SCIENCE BY *FAST COMPANY*

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