A Message from
Samin K. Sharma, MD and
Annapoorna S. Kini, MD

Dear Colleague

From the Cardiac Catheterization Laboratory at The Mount Sinai Hospital, we are proud to present our patient-centered 2016 Clinical Outcomes & Innovations Report, a comprehensive overview of the work being done at one of the nation’s finest cardiac catheterization laboratories. Public reporting of quality outcomes and patient safety data is increasingly being mandated for transparency by various organizations and stakeholders. As we have done each year, in this issue, we also report our performance metrics and compare them to regional and national standards, with the goal of providing the highest level care to our heart patients.

Our catheterization laboratory continues its relentless drive for procedural excellence, pursuing and developing the latest technical and technological advances in the field of percutaneous coronary intervention (PCI). Our procedural outcomes data over the last five years support the statement that we have perfected the art of PCI.

The management of stable coronary artery disease (CAD) patients is rapidly changing, with medical therapy playing a major role in the routine management of CAD patients and PCI being used in moderate to severe CAD, as well as in patients with acute coronary syndrome. Patients with extensive CAD are best treated with coronary artery bypass graft surgery (CABG) to improve long-term survival. Overall rates of percutaneous and surgical revascularization have been decreasing over the years due to guidelines directing optimal medical management of CAD patients. Despite the increasing complexity of PCI cases, we have observed an overall decline in complications of PCI because of our expertise, teamwork, and dedication in treating each patient as an individual. We are committed to the universal use of innovative and evidence-based standardized medical protocols, which have contributed to our extraordinary success. It is not unusual for patients who have been deemed “inoperable for advanced extensive cardiac disease” to come to us, be treated successfully, and go home with smiles on their faces.

In order to remain at the top, we will continue to employ cutting-edge technology and techniques that are now the hallmarks of our success. In this issue, we will provide details of several procedures that are routinely done at our center, as well as their volume and outcomes. Our constantly evolving, innovative approaches have contributed to our national and international recognition, and we highlight these innovations through the words of our grateful patients. Our goal for 2017 is to rise to eminence from excellence by innovation and well-organized comprehensive care in the field of interventional cardiology.
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For more information, visit [www.mountsinai.org/interventional-cardiology-cath-lab](http://www.mountsinai.org/interventional-cardiology-cath-lab)
The Mount Sinai Hospital Cardiac Catheterization Laboratory has demonstrated many years of excellent quality and outcomes. The safety record is impressive, especially in light of the growing numbers of complex interventions for coronary, valvular, congenital, and structural heart diseases. The safety record in outcomes registry results and the strong research output speak to the excellence of the clinical and research teams. It is therefore a pleasure to introduce this eighth edition of the Cardiac Catheterization Laboratory Clinical Outcomes & Innovations Report.

The leadership of Samin K. Sharma, MD and Annapoorna S. Kini, MD and the dedication of the teams of physicians, advanced practice nurses, physician assistants, and technical staff are inextricably linked to the superb safety record. The team’s dedication to continuous quality improvement, extensive data analysis, and patient satisfaction exemplifies The Mount Sinai Hospital’s commitment to its missions of clinical care, education, and research.

We hope you find this eighth edition of the Cardiac Catheterization Laboratory Clinical Outcomes & Innovations Report to be informative.
A Message from
Valentin Fuster, MD, PhD, MACC

You don’t have to travel far to meet a patient who has been touched by the remarkable talent and compassion of the Mount Sinai Cardiac Catheterization Laboratory, which has treated thousands of patients from across greater New York for more than ten years. Samin Sharma, MD and Annapoorna Kini, MD continue to lead not only the catheterization laboratory, but, in many ways, the field of interventional cardiology.

The Mount Sinai Hospital was an early pioneer in percutaneous coronary intervention (PCI), which revolutionized diagnosis and treatment for coronary artery disease; and they have continued to perfect the art of PCI. But the interventional cardiologists and staff at the Cardiac Catheterization Laboratory continue to push forward, pioneering and adopting the latest treatments not just for coronary artery disease, but for a full range of heart issues, from congenital defects to damaged valves.

That dedication to advancing the standard of care for patients is only possible with an equally vigorous commitment to research and clinical trials, and investments in the next generation of interventional cardiologists through robust education and fellowship programs.

In this issue of the Clinical Outcomes & Innovations Report, we reflect on the continued procedural success by reviewing our outcomes and discussing exciting new frontiers such as genetic implications for coronary artery disease, or the connection between the nerves of the kidneys and a patient’s blood pressure.

Finally, we share the voices of patients who have benefited from the talent, technique and humanity of our own Cardiac Catheterization Laboratory.
An Overview of Services and Outcomes

“Success is the result of perfection, hard work, learning from failure, loyalty, and persistence.”

– General Colin Powell

These powerful words sum up the key principles of the successful operations at our Cardiac Catheterization Laboratory. The Cardiac Catheterization Laboratory at The Mount Sinai Hospital is among the highest volume, safest interventional catheterization laboratories in the United States. Consisting of six adult catheterization rooms (three equipped for endovascular procedures), the Cardiac Catheterization Laboratory is established as a 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 (IVUS) and fractional flow reserve (FFR) capabilities and optical coherence tomography (OCT). In addition, we have access to the hybrid OR suite to perform certain TAVR cases especially requiring complex vascular access.

Each member of the Cardiac Catheterization Laboratory staff has a strong work ethic and takes pride in his or her contribution to the principal goal of our catheterization laboratory: delivery of efficient and safe care to patients in need. As a result, the Cardiac Catheterization Laboratory consistently reports a very high level of patient satisfaction.
One very important aspect of patient satisfaction is making the in-hospital stay as short as possible. With this in mind, approximately 68 percent of our elective interventional patients are safely discharged on the day of the procedure (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.

The volume of diagnostic catheterization and interventional procedures at the Cardiac Catheterization Laboratory at The Mount Sinai Hospital is shown in the graph on this page.

Total percutaneous interventions encompass percutaneous coronary interventions (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 (TAVR/TAVI) for stenosed aortic valves, MitraClip® for high-risk mitral regurgitation, transcatheter mitral valve replacement (TMVR) for dysfunctional bioprosthetic mitral valve, and alcohol septal ablation for hypertrophic obstructive cardiomyopathy (HOCM).

The percent distribution of different types of coronary interventions is shown in the figure on this page, highlighting the unusually high volume of atherectomy (20 percent), largely due to selective referral of complex calcified lesions to our lab from other centers in the region and nationwide. Overall use of drug-eluting stents (DES) in our PCI procedures is >98 percent.
The system of established standard protocols, rigorous attention to minute detail, and a strong sense of teamwork have helped us to achieve the best interventional outcomes in the country. Overall angiographic success of non-CTO lesions remains over 99% in our Catheterization Laboratory. We continue to improve our outcomes every year, with unprecedented low procedural complications in 2016; combined major complications of death, large MI, urgent CABG, and CVA cases was approximately 0.85 percent. This remarkably low complication rate has been achieved despite high complexity and comorbid medical conditions of patients treated in the Cardiac Catheterization Laboratory.

Comparison of Mount Sinai Hospital Intervventional Outcomes With New York State Data for 2013

Our Cardiac Catheterization Laboratory continues to serve the full range of cases, from simple to the most complex cases with high clinical comorbidities and complex angiographic characteristics. Despite that added complexity, the majority of PCI complications at The Mount Sinai Hospital have been one-third to one-half of the New York State Department of Health results.

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 Hospital Cardiac Catheterization Laboratory among the lowest for in-hospital and 30-day risk-adjusted mortality. The most recent New York State Department of Health report of 30-day risk-adjusted mortality rate (RAMR) for year 2011-2013 has shown our incidence of 0.75 percent for all cases, 0.49 percent for elective cases, and 2.17 percent for emergency PCI cases, which is about 30 percent lower than the statewide average. In the latest 2011-2013 PCI report, we are one of three centers to receive a double-star (**) notation of superior safety in at least two PCI categories (all cases and non-emergency cases); receiving the double star denoting statistically significantly lower RAMR than the statewide average has been a constant over the last 17 years of New York State Department of Health PCI reporting.

This lower 30-day risk-adjusted mortality 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. Our interventionalists frequently get double star notations (**) for PCI safety among 600 interventionalists practicing in the state.
<table>
<thead>
<tr>
<th>PCI Statistics 2011-2013</th>
<th># Cases</th>
<th>All Cases</th>
<th>Non-Emergency Cases</th>
<th>Emergency Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. The Mount Sinai Hospital</strong></td>
<td>13,906</td>
<td>0.75**</td>
<td>0.49**</td>
<td>2.17</td>
</tr>
<tr>
<td>2. Columbia Presbyterian Hospital</td>
<td>8,342</td>
<td>0.76**</td>
<td>0.52</td>
<td>2.00</td>
</tr>
<tr>
<td>3. Saint Francis Hospital</td>
<td>7,230</td>
<td>0.97</td>
<td>0.62</td>
<td>3.00</td>
</tr>
<tr>
<td>4. Saint Joseph’s Hospital</td>
<td>6,283</td>
<td>0.92</td>
<td>0.69</td>
<td>2.02</td>
</tr>
<tr>
<td>5. LIJ Medical Center</td>
<td>5,158</td>
<td>0.88</td>
<td>0.73</td>
<td>1.31</td>
</tr>
<tr>
<td>6. Lenox Hill Hospital</td>
<td>4,862</td>
<td>0.75</td>
<td>0.40**</td>
<td>2.70</td>
</tr>
<tr>
<td>7. Rochester General Hospital</td>
<td>4,825</td>
<td>1.25</td>
<td>0.66</td>
<td>4.30*</td>
</tr>
<tr>
<td>8. Buffalo General Hospital</td>
<td>4,730</td>
<td>1.43*</td>
<td>0.97*</td>
<td>3.68</td>
</tr>
<tr>
<td>9. North Shore University Hospital</td>
<td>4,507</td>
<td>0.69**</td>
<td>0.54</td>
<td>1.40**</td>
</tr>
<tr>
<td>10. Beth Israel Medical Center</td>
<td>4,484</td>
<td>1.14</td>
<td>0.79</td>
<td>3.05</td>
</tr>
<tr>
<td><strong>NYS Total</strong></td>
<td>145,247</td>
<td>1.04</td>
<td>0.68</td>
<td>2.81</td>
</tr>
</tbody>
</table>

www.nyhealth.gov  
*Risk Adjusted Mortality Rate (RAMR) significantly higher than statewide rate  
**Risk Adjusted Mortality Rate (RAMR) significantly lower than statewide rate
The American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR) reports the characteristics and in-hospital outcomes after PCI of more than 1,400 hospitals in the United States providing data of 1.4 million PCI patients.

Following are the important baseline and procedure characteristics of The Mount Sinai Hospital (MSH) versus ACC-NCDR hospitals. The graphs on these pages show the superior outcomes of PCI patients at The Mount Sinai Hospital in comparison to other U.S. hospitals in the ACC-NCDR report for 2015.
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 federal agencies or insurance companies. At Mount Sinai Heart, we established evidence-based protocols of proper evaluation of CAD patients before scheduling for catheterization and possible intervention and then rigorous application of the appropriate use criteria (AUC) of the American College of Cardiology; this has yielded one of the lowest rates of inappropriate PCI for stable CAD in the nation. Fractional flow reserve (FFR) has been increasingly adopted in our clinical practice, guiding the decision making for appropriate PCI.

The rate of PCI procedures performed in less than 90 minutes is an important quality CMS parameter and is publicly reported for all hospitals. The proportion of STEMI patients at The Mount Sinai Hospital undergoing PCI in less than 90 minutes was 88 percent in 2015. According to the 2015 ACC/NCDR Report, risk-adjusted mortality of STEMI patients at The Mount Sinai Hospital is approximately 50 percent lower than that of other comparable U.S. hospitals.
Key Points

• We employ a heart team approach in complex coronary cases where the patient consults with a cardiologist, cardiothoracic surgeon, and cardiac interventionalist to determine the best course of treatment.

• For patients with comorbidities, including diabetes and extensive multivessel disease, studies have demonstrated CABG surgery is associated with better long-term survival than PCI.

• At The Mount Sinai Hospital, we have been recommending surgery for patients with complex CAD, and 60 percent of patients have complied with that recommendation.

• We continue to participate in studies to ensure we pursue the best outcomes for every patient.

Data from several large, multicenter clinical trials continue to inform our approach to clinical decision making for coronary revascularization. Two major trials of multivessel coronary artery disease (CAD), the SYNTAX (SYNergy Between Percutaneous Coronary Intervention with TAXus and Cardiac Surgery) and FREEDOM (Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease) trials, have established a definite role for coronary artery bypass surgery (CABG), over percutaneous coronary intervention (PCI) with low long-term mortality and myocardial infarction (MI) but higher stroke rates compared to PCI. The SYNTAX trial employed a novel grading tool, known as the SYNTAX Score, to assess the complexity of CAD based on several anatomical factors.

To view two prerecorded cases featuring protected high risk and bifurcation PCI, scan the QR codes above.
Patients with a high SYNTAX Score (>32) were shown to have better five-year survival rates after CABG than after PCI. Ultimately, the decision to either have surgery or PCI lies with the patient and his or her family, after consultation with the heart team, which includes a cardiologist, cardiothoracic surgeon, and cardiac interventionalist. Many patients with complex CAD choose revascularization with PCI, due to lower short-term complications and relative ease of recovery compared with surgery. Data collected over the last several years at The Mount Sinai Hospital reveal that a majority of our patients with complex CAD complied with recommendations to have CABG surgery. Based on this evidence, there is an increasing tendency at The Mount Sinai Hospital toward recommending surgery for patients with more complex CAD.

PATIENT: Charanjit Singh, 53-year-old male
DIAGNOSIS: Three-vessel CAD with 2 CTOs
TREATMENT: PCI including PCTA and placement of five DES

“Now I feel perfect, like I'm even younger—maybe even 16 years old.”

“Although I'm quite young, I had visited so many hospitals for what was found to be blockages in my arteries. Everyone wanted to do a bypass surgery, but at my age, I knew that I didn't want to face a big surgery like that if it was avoidable. One of my doctors recommended seeing Dr. Sharma. He said, 'He is the best doctor in the world and if he can't help you, no one can.' He was absolutely right. When I went to meet Dr. Sharma, he saw me in the waiting room and couldn't believe that I was a patient. He said he would place my stents right away, that very same day. He was done within 45 minutes—five stents—and I had no pain at all. When Dr. Sharma went to tell my family the good news, they were all dancing! Now I feel perfect, like I'm even younger—maybe even 16 years old—and after each day at work, I still feel fresh. Believe me, he's the #1 doctor in the world, and he's very special, not just for me, but for everyone.”
Since the conclusion of the SYNTAX and FREEDOM trials in 2008-2010, in which patients in the PCI arm were treated with the sirolimus- or paclitaxel-eluting stent (first generation drug-eluting stents (DES)), a newer generation of DES systems have arrived in clinical practice. These newer stents, such as the zotarolimus-eluting stent and the everolimus-eluting stent, have thinner struts and are associated with better healing causing lower restenosis and lower thrombosis. Data from a registry-based study of 34,819 patients with multivessel CAD revealed that patients who underwent PCI with an everolimus-eluting stent had a lower short-term risk of death and stroke compared with those who had CABG surgery. However, PCI was associated with a higher risk of repeat revascularization and myocardial infarction (MI) and no difference in death at long term. The latest generation of coronary stents incorporates biodegradable polymers that may even further reduce late thrombosis. The trial of bioabsorbable vascular scaffold (BVS) ABSORB II, comparing BVS with Xience DES, has shown higher MI and stent thrombosis at three-year follow-up. As a result, BVS use is kept at a minimum in our interventional practice. Another recent trial comparing Xience DES with CABG in unprotected left main disease (EXCEL Trial) with Syntax Score <32 has shown equal results after both modes of revascularization. Additional studies that take these design changes into account, combined with the use of more advanced imaging modalities before and during procedures, may tip the balance in favor of recommending PCI as first-line therapy for more patients with moderate to severe CAD.

In addition to expertise in treating multivessel CAD with PCI, our Catheterization Laboratory also serves as a tertiary center for complex coronary intervention (bifurcation, calcified, left main, CTO, and/or vein graft lesions) and patients with low ejection fraction (LVEF <35 percent). We use a variety of adjunct interventional techniques in these complex coronary cases, such as atherectomy (for calcified lesions, 20 percent) and thrombectomy/distal protection devices (for thrombotic and vein graft lesions, in 3 percent).

In a small number of complex lesion patients (=5 percent of PCI) with reduced ejection fraction (LVEF <35 percent) we use LV assist devices such as IABP, Impella or ECMO to safely and dependably perform these high-risk PCI (protected PCI).
Intravascular Brachytherapy (IVBT) for Recurrent DES In-Stent Restenosis

Patients presenting with recurrent in-stent restenosis (ISR) of DES with more than two layers of stents are appropriate cases for IVBT using the Beta-Cath™ System to reduce subsequent restenosis. Our IVBT data over the last five years have shown excellent acute outcomes with <1 percent major complications, no need for implantation of another stent and long-term restenosis of 25 percent (compared to 55 percent in comparable recurrent DES ISR without IVBT).

References:
A chronic total occlusion (CTO) is defined as a complete obstruction in a coronary artery that has been present for longer than three months. CTOs are commonly encountered in everyday practice in the cardiac catheterization laboratory and are identified in up to 20 percent of all patients who are referred for diagnostic angiography.

Numerous smaller collateral blood vessels are generally well-developed in the region outside of a CTO, the blood flow through these vessels is similar to having a 90 percent coronary stenosis and is often insufficient, even at rest. Patients with CTOs often have atypical symptoms, such as shortness of breath and exercise limitations, rather than the typical angina pain that occurs in patients with less severe blockages. Several observational studies have demonstrated that successful CTO revascularization is associated with improved long-term survival and enhanced quality of life.

Recently, considerable progress has been achieved in percutaneous coronary interventions (PCI) for patients with CTOs. Important developments in dedicated equipment and techniques have resulted in high rates of success and low rates of complications, even in complex CTO cases. Coronary computed tomography angiography is a noninvasive imaging modality that enables the precise assessment of CTO lesions.

Specialized guidewires, micro-catheters and small balloons have made it easier to penetrate complex CTO lesions. In rare calcified cases, CTO lesions can be tackled by using rotational and laser atherectomy. Recently the EXPERT CTO Trial in the U.S. demonstrated wire success rates of >90 percent, procedural success >96 percent, significant perforation =0 percent, and very low follow-up events at one year (<10 percent).

Our expert interventionalists have achieved high success rates in revascularizing CTOs, using both antegrade and retrograde approaches. The antegrade approach has been the conventional method of treating a CTO. The retrograde approach, which involves reaching the CTO via its collateral channel, has improved success rates in patients with complex CTOs that are not amenable to the antegrade technique.

References:
Simply put, Dr. Kini saved my life.
Feeling alarmingly short of breath, I went to the emergency room of my local hospital. Their initial tests showed fluid on my lungs and what they called low ejection fraction—I was diagnosed with congestive heart failure. My primary care physician referred me to a hospital with a highly regarded cardiac department where an angiogram revealed two major coronary arteries almost completely blocked. They told me that it was so severe that there was nothing they could do but insert a defibrillator and pacemaker. The decision to get a second opinion was among the best I ever made. After some research, I made an appointment with Dr. Kini, who evaluated me and reassured me that she could help. Boy! Did she ever! I had two procedures to place a total of five stents. For each procedure, I stayed overnight so they could monitor me. My ejection fraction went from a low of 15 percent to the current 53 percent. I was given a new lease on life. My experience was as close as a hospital stay can ever be to pleasant. The entire staff was caring and professional. It’s truly difficult to find words to express my gratitude and appreciation for Dr. Kini. The woman is remarkable—a miracle worker—and her skills far surpass that of other doctors.”
In multiple trials of transcatheter aortic valve replacement (TAVR) in various surgical risk (STS Score) patients have shown that it is an important therapeutic option for patients with severe, symptomatic calcific aortic stenosis (AS) who are extreme or high risk for cardiac surgery due to serious comorbidities.

The Mount Sinai Hospital continues to participate in clinical research to improve TAVR outcomes in patients with severe AS. Recently, the PARTNER II A Trial—comparing TAVR in more than 2,000 AS patients who are randomized to receive the SAPIEN XT or SAPIEN-3 device TAVR with current surgical aortic valve replacement (SAVR) technique in intermediate risk AS patients—showed that TAVR outcomes are similar to SAVR with reduced hospital stay, low morbidity, and even lower mortality in transfemoral cases.

The Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) Trial is a multicenter clinical trial comparing percutaneous implantation of a self-expanding EVOLUT-R CoreValve® System with surgical valve replacement in patients with severe aortic stenosis and intermediate risk for surgery. The results will be presented in ACC 2017.

Expanding the Horizons of Transcatheter Aortic Valve Replacement (TAVR)

Samin K. Sharma, MD  Annapoorna S. Kini, MD

In multiple trials of transcatheter aortic valve replacement (TAVR) replacement (TAVR) in various surgical risk (STS Score) patients have shown that it is an important therapeutic option for patients with severe, symptomatic calcific aortic stenosis (AS) who are extreme or high risk for cardiac surgery due to serious comorbidities.

The Mount Sinai Hospital continues to participate in clinical research to improve TAVR outcomes in patients with severe AS.

We are always evaluating new imaging techniques to ensure ideal placement and enhance the success rates of TAVR devices in our patients.

Although TAVR is associated with faster recovery and fewer complications, appropriate discharge planning is vital to ensuring that success.

Patient education, medication adherence, follow-up, and coordination with the patient’s cardiologist and PCP are vital to optimal outcomes.

To view a prerecorded case featuring SAPIEN 3-TAVR, scan the QR code above.

Edwards SAPIEN® Valve

Medtronic CoreValve®

Balloon Expandable, Bovine Valve

Self-Expanding, Porcine Valve

Key Points

• Mount Sinai Heart was an early pioneer in TAVR therapy for patients with severe aortic stenosis (AS).

• The Mount Sinai Hospital has participated in trials including the CoreValve, SURTAVI and Low-Risk Evolut-R trials, and continues to participate in clinical research to improve TAVR outcomes in patients with severe AS.

• We are always evaluating new imaging techniques to ensure ideal placement and enhance the success rates of TAVR devices in our patients.

• Although TAVR is associated with faster recovery and fewer complications, appropriate discharge planning is vital to ensuring that success.

• Patient education, medication adherence, follow-up, and coordination with the patient’s cardiologist and PCP are vital to optimal outcomes.
PATIENT: John O'Connor, 73-year-old male
DIAGNOSIS: Aortic stenosis and insufficiency
TREATMENT: Placement of CoreValve

“The very next day, I was already sitting up in bed with breakfast, my newspaper, and no pain or discomfort.”

““In 2011, I went to a local hospital to have stents placed, but when they found that my condition was worse than expected, they rushed me in for a triple bypass. I spent a week in the hospital recovering from that invasive procedure. I remained under the care of my cardiologist, who said that I would need a new valve—while a healthy valve opens to the size of a quarter, mine was only opening to the size of a pencil eraser. He referred me to Dr. Sharma, and from the first interview with him and his team, I was at ease. My previous procedure put me at high risk for a surgical valve replacement, even though I would otherwise be at a low risk. Dr. Sharma and his team assured me that the TAVR procedure was the best option, and they were right. From then on, I didn’t call him Dr. Sharma, I called him Superman. He made the procedure seem so simple, and the very next day, I was already sitting up in bed with breakfast, my newspaper, and no pain or discomfort. He made sure that I was on my way home by the end of the week. After I had my bypass, my breathing was still sluggish, and it would take me at least 35 minutes to walk one mile. Now it takes me less time, and I’m up to two miles a day. When I took a trip down to Florida, I even walked five miles, counting all the walking in the airport. It’s a miracle, an absolute miracle.”

PARTNER 2A Trial: 2-Year Clinical Outcomes in High Risk Aortic Stenosis

PARTNER 2A Trial: Primary Endpoint (AT)
All-Cause Mortality or Disabling Stroke

p=0.04

2016 Clinical Outcomes & Innovations Report
PATIENT: Carol Levi, 67-year-old female
DIAGNOSIS: Aortic valve stenosis
TREATMENT: TAVR using SAPIEN valve

“When Dr. Sharma told us that I was approved for this amazing new TAVR procedure and didn’t need open heart surgery, I was so grateful.”

“For the past five years, I experienced fatigue all the time. Even at work, I would get tired walking from one office to the next, or I would fall asleep at my desk. A week before my son’s wedding, I had tests done with my cardiologist: They told me I would need open heart surgery, and I was shocked. I had no idea that my symptoms could have been related to my heart. I didn’t want to say anything to my family because I didn’t want to take away from the wedding, but my daughter, Randi, knew something was up. I finally told her, and then my son when he returned from his honeymoon. Randi really took charge! She researched doctors in the area and got a recommendation from a friend at Mount Sinai to go see Dr. Sharma because ‘he’s the best.’ As soon as we met with Dr. Sharma, he knew what I needed right away. I’ve had diabetes for many years and I don’t heal well, so Randi made a case for me not to get open heart surgery. When Dr. Sharma told us that I was approved for this amazing new TAVR procedure and didn’t need open heart surgery, I was so grateful.

The people at Mount Sinai are incredible. Just two weeks later they did my TAVR procedure and when I was there, I always knew that I had lots of people right there taking care of me. I said that if I got through this, I was going to go on a cruise with my grandchildren, Randi, and her husband. We just got back and had such a good time!”

The Mount Sinai Hospital is enrolling patients in the EVOLUT-R Low Risk Trial which is evaluating TAVR vs. SAVR in low STS risk (<3 percent) AS patients.

Another study (SENTINEL Trial) to assess the risk of stroke in patients who have TAVR with the Sentinel Cerebral Protection System (which is an embolic filter that is designed to trap calcified deposits that become dislodged during the TAVR procedure), showed that use of the Sentinel device is associated with lower risk of brain infarction (42 percent) with a trend toward lower stroke rates compared to a control group.

Cardiologists at The Mount Sinai Hospital routinely employ three-dimensional transesophageal echocardiography (3D TEE echo), and 4D computed tomography (CT) to better evaluate the TAVR procedure. Image quality and details are highly relevant to the
success of TAVR, which relies on the appropriate evaluation and measurement of the aortic annulus to prevent complications such as paravalvular leak, prosthesis migration, coronary artery occlusion, or annulus rupture.

The Mount Sinai Hospital was one of the earliest centers to demonstrate the safety of TAVR with 3D transthoracic echo (3D TTE), in which patients are given conscious sedation (done in = 60 percent of cases) and avoiding general anesthesia. This approach is associated with fewer complications, faster recovery time and less procedural time than 3D TEE, which requires the patient to be intubated during general anesthesia.

The Mount Sinai Hospital was the first center in the United States to deploy the CoreValve® in December 2010. Since then, our TAVR volume and outcomes have improved significantly. Our TAVR data is regularly submitted to the national TVT registry.

References:

TAVR Outcomes at Mount Sinai Hospital 2016
-68% Evolut-R CoreValve, 32% SAPIEN-3
-60% Conscious Sedation; 40% General Anesthesia
-80% Perc Femoral; 10% Cutdown Iliac; 9% Subclavican;
1% Direct Aortic
n=278
Annapoorna S. Kini, MD

Mitral valve regurgitation is a common valve disorder that causes blood to leak backward through the mitral valve and into the left atrium as the heart muscle contracts. Mitral regurgitation can originate from degenerative or structural defects due to aging, infection, or congenital anomalies. In contrast, functional mitral regurgitation occurs when coronary artery disease or events such as a heart attack change the size and shape of the heart muscle, preventing the mitral valve from opening and closing properly. In people with moderate to severe mitral regurgitation, the left ventricle works harder to keep up with the body's demand for oxygenated blood. Over time, this dysfunction can lead to enlargement of the left ventricle, weakening of the myocardium and pulmonary hypertension.

Surgery — either to repair or replace a leaky mitral valve — has been the principal therapeutic option for patients with chronic, severe mitral regurgitation that is not controlled with medication. A less invasive option, which involves transcatheter implantation of a device that essentially sutures the valve leaflets and increases their coaptation, is indicated for patients with severe degenerative mitral regurgitation who are at high risk for conventional heart surgery.

The EVEREST (Endovascular Valve Edge-to-Edge Repair Study) II Trial was a randomized study comparing the transcatheter approach using MitraClip® — a tiny cobalt chromium clip that sutures the anterior and posterior mitral valve leaflets — with surgery in patients with moderate to severe mitral regurgitation who are candidates for either procedure. After five years, the study has demonstrated that MitraClip was associated with a similar risk of death compared with mitral valve surgery after excluding patients who required surgery within six months. However, patients who were treated with the MitraClip had a significantly higher rate of residual mitral regurgitation at five years after the procedure compared with those who had surgery (14 percent versus 3 percent).

Another clinical trial, COAPT (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation), is now getting underway in 100 U.S. sites. The study will compare transcatheter mitral valve repair with standard therapy — medications, pacemaker implantation, or other treatments — and standard therapy alone in approximately 610 patients.
I have spent time at the hospital for heart failure, and it seemed my condition was getting worse. I was having trouble breathing and could hardly walk around the neighborhood, or even around my home. My valves were the problem, but I was afraid to have a major operation to fix them. During one of my follow-up visits to my cardiologist, he told me they were getting too bad, and he said the doctor to see was Dr. Sharma.

“When I met with Dr. Sharma, he immediately set me at ease. He could see the problem and offered a clear solution. Since I was a high-risk case for surgery, he recommended a tiny clip that would stop the leakage in my mitral valve. The procedure went smoothly and I was out in two weeks—by that time, everyone at the hospital didn’t realize there had been anything wrong with me! This past Christmas Eve, I was able to walk up two flights of stairs at my family’s house and then down those stairs on Christmas Day. I walked even more that day to visit family, and my granddaughter said I was walking better than her 60-year-old father—and I’m almost 90!

Everyone at Mount Sinai Hospital was very good and very caring, especially Dr. Sharma.”

PATIENT: Teresa Kukura, 89-year-old female
DIAGNOSIS: MV insufficiency
TREATMENT: Transcatheter mitral valve repair using MitraClip®
INNOVATIONS

Transcatheter Mitral Valve Replacement (TMVR)

Annapoorna S. Kini, MD  George Dangas, MD  Asaad A. Khan, MD

Transcatheter mitral valve replacement (TMVR) has emerged as an important option for high surgical risk patients who present with symptoms because of valve deterioration after tissue mitral valve replacement. These patients may present with shortness of breath, fainting, dizziness, tiredness, chest pains (angina), and atrial fibrillation.

TMVR can be performed via access in the blood vessels of the groin area or via chest (apex of the heart) and avoids the need for cutting open the chest wall, stopping the heart, and putting patients on bypass. In our experienced center, the procedure itself can take from two to three hours. Sometimes it can be longer depending on the complexity of the case.

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Mount Sinai has significant experience in successfully performing TMVR procedures with excellent safety and long-term outcomes.

In our experienced center, the procedure itself can take from two to three hours. Sometimes it can be longer depending on the complexity of the case. Following the procedure, the patients are closely monitored for one to two days. We are particularly attentive to arrhythmias and changes in blood results.

By performing a comprehensive echocardiogram of the heart within 24 hours of the procedure, we assess the function of the new mitral valve and rule out any possible complications.

Reference:

Alcohol Septal Ablation (ASA)

Annapoorna S. Kini, MD

Hypertrophic obstructive cardiomyopathy (HOCM) is typically genetic in nature and reveals itself in the second or third decade of life. Patient complaints include exertional chest pain, shortness of breath, fatigue, fainting, and palpitations. Rarely, sudden death can occur. There are a range of treatments available for symptomatic HOCM. First-line treatment consists of medical management with drugs such as beta-blockers, calcium channel blockers, and other negatively inotropic medications (drugs that slow the heart rate and improve the filling of heart). For patients with persistent symptoms, the recommended treatment is open-heart surgery and surgical removal of the overgrown heart muscle (septal myectomy) to enhance blood flow from the left ventricle.

The Mount Sinai Cardiac Catheterization Laboratory is one of the relatively few high-volume centers offering a select group of HOCM patients with refractory or persistent symptoms another choice, alcohol septal ablation (ASA). This minimally invasive procedure does not require general anesthesia or lengthy recovery time and is rarely associated with complications of open-heart septal myectomy.

While selecting patients for this procedure, we follow certain standards based on echocardiographic assessment of the hypertrophic heart muscle. Thicknesses less than 16 mm typically respond to medical management while septa thicker than 26mm should not undergo ASA.

ASA is performed percutaneously, eliminating the need for surgery, but yields similar results in terms of removing overgrown heart muscle. This procedure involves injecting 98 percent alcohol via catheter into a carefully selected artery that supplies blood to the overgrown tissue in the enlarged septum. The highly-concentrated alcohol is injected slowly (1-3cc/second) directly into the heart muscle and is left in place for several minutes. The treatment effect starts immediately by causing controlled cell death at the target location. Typically, the goal is to remove no more than two grams of obstructive muscle mass, as complications such as irregular heart beat can occur if a more aggressive approach is used, necessitating a permanent pacemaker. Strict adherence to our highly cautious patient selection protocols, complemented by extremely efficient post procedure management in CCU, has helped optimize our outcomes.

Following the procedure, patients are closely monitored in ICU for two days with a temporary pacemaker inserted via the jugular vein in the neck with particular attention paid to heart rhythm and changes in blood chemistry. Approximately 10 percent of the patients after ASA will require a permanent pacemaker due to persistent heart block. Patients typically report immediate improvement in their symptoms and once safely stabilized, are able to go home with minimal restriction on physical activity for the following two to four weeks. The ablative process completes over several weeks as a thin layer of scar tissue forms and LV diastolic function improves. We do follow-up echocardiograms of the post-operative patient in three to six months.

Reference:
YELLOW (Reduction in Coronary Yellow Plaque, Lipids and Vascular Inflammation by Aggressive Lipid Lowering) II study

Many studies have demonstrated the benefits of statins in reducing mortality and frequency of myocardial infarction, and provided strong evidence for their effective suppression of inflammation and other lipid-lowering independent properties. The pleiotropic (multiple simultaneous) effects of statins also contribute to favorable changes in plaque biology documented by multiple intravascular imaging studies. High-intensity statin therapy significantly reduced atheroma volume assessed by intravascular ultrasound (ASTEROID trial) and altered plaque lipid content when measured by near infrared spectroscopy (YELLOW trial). Inspired by the findings of our YELLOW trial, we designed the YELLOW II study to provide a wider snapshot of how high-dose statin therapy exerts its influence on plaque morphology by assessing cholesterol efflux capacity (CEC) to see exactly how lipid is removed from the plaque. We have also included gene expression analysis of patient’s peripheral blood mononuclear cells (PBMC).

The study included 85 patients with stable multivessel coronary artery disease who underwent percutaneous coronary intervention (PCI) for a culprit lesion. Patients were treated with rosuvastatin 40 mg for 8 to 12 weeks, and then follow-up imaging was performed. During the study period, total cholesterol levels were reduced from 153.3 mg/dL to 115.0 mg/dL, while LDL cholesterol decreased from 87 mg/dL to 50.6 mg/dL. In addition, there was an improvement in the apolipoprotein profile, while C-reactive protein (CRP) levels also declined. There was a significant increase in the fibrous cap thickness (FCT) resulting in the reduction of the prevalence of thin-cap fibroatheroma (TCFA), a high-risk plaque vulnerable to rupture, from 20 percent to 7 percent (P = 0.003). We also observed significant improvements in Cholesterol Efflux Capacity (CEC), which measures the ability of HDL to promote the removal of cholesterol from lipid-laden plaque macrophages. This is one of the initial steps in reverse transport that takes cholesterol from the periphery to the liver. On multivariate analysis, the change in fibrous cap thickness was independently associated with the increase in CEC.
Out of a total of 20,819 genes assayed using microarray, we identified 117 differentially expressed genes before and after high-dose statin therapy, six of which were involved in cholesterol synthesis (SQLE), regulation of fatty acid unsaturation (FADS1), cellular cholesterol uptake (LDLR), cholesterol efflux (ABCA1, ABCG1), and inflammation (DHCR24). These transcriptomic changes in the patient’s peripheral blood may have potential for being developed as a biomarker to predict patients who will favorably respond to maximum dose of statins by demonstrating improvements in plaque morphology and cholesterol efflux capacity and not simply reductions in LDL cholesterol levels.

The YELLOW II study demonstrated favorable modulation in different markers of coronary atherosclerotic plaque vulnerability among patients treated with high-intensity statins for a short duration. In part, these changes may be attributable to enhanced CEC, an independent correlate of increased FCT in our study. We also demonstrated that significant transcriptomic perturbations related to cholesterol synthesis, regulation of fatty acid unsaturation, cellular cholesterol uptake, efflux, and inflammation may cooperate in determining the beneficial effects of statins on plaque stabilization.

Reference:
Maintaining healthy blood pressure is one of the most important ways patients can remain healthy. Over the long term, hypertension can impact the heart, kidneys, and other systems in the body. It can lead to many dangerous conditions including stroke, heart disease, kidney failure, and arterial disease.

Resistant hypertension is defined as blood pressure that remains above the goal despite concurrent use of three antihypertensive agents of different classes, one of which should be a diuretic. Patients whose blood pressure is controlled with four or more medications are considered to have resistant hypertension.

According to the World Health Organization (WHO), hypertension is the most frequent cause of death worldwide (7.5 million deaths annually). Estimates show that by 2025, 50 percent of the adult population will be hypertensive. Twenty to 30 percent of patients are considered to have resistant HTN despite the availability of potent medications. A 20/10mmHg increase in blood pressure doubles cardiovascular mortality. Reduction of systolic blood pressure by only 10 mmHg reduces the risk of stroke by 30 percent.

Astonishingly, only half of all treated hypertensive patients are controlled to established blood pressure targets. Renal sympathetic activation plays a key role in the pathogenesis of hypertension, as demonstrated by high renal norepinephrine spillover into plasma of patients with essential hypertension. Renal denervation has demonstrated a significant reduction in blood pressure in unblinded studies of hypertensive patients. It consists of a catheter that delivers a precise amount of energy to the sympathetic nerves in the kidney and, as a result, improves blood pressure control.

The SYMPLICITY HTN-3 trial, the first prospective, masked, randomized study of renal denervation versus a placebo intervention control, failed its primary efficacy endpoint and raised important questions around potentially confounding factors, such as drug changes and adherence, study population, and procedural methods.

### Renal Sympathetic Activation: Efferent Nerves

Kidney as Recipient of Sympathetic Signals

- Renin Release → RAAS activation
- Sodium Retention
- Renal Blood Flow

### Renal Sympathetic Activation: Afferent Nerves

Kidney as Origin of Sympathetic Drive

- Vasoconstriction
- Atherosclerosis
- Insulin Resistance
- Sleep Disturbances
- Hypertrophy
- Arhythmia
- Oxygen Consumption
- Renin Release → RAAS activation
- Sodium Retention
- Renal Blood Flow
The SPYRAL HTN Global Clinical Trial Program is designed to address limitations associated with predicate studies and provide insight into the impact of pharmacotherapy on renal denervation efficacy.

The two initial trials of the program focus on the effect of renal denervation using the new multielectrode renal denervation catheter in hypertensive patients in the absence (SPYRAL HTN OFF-MED) and presence (SPYRAL HTN ON-MED) of antihypertensive medications. The SPYRAL HTN ON-MED study requires patients to be treated with a consistent triple therapy antihypertensive regimen, whereas the SPYRAL HTN OFF-MED study includes a three- to four-week drug washout period followed by a three-month efficacy and safety endpoint in the absence of antihypertensive medications. The studies will randomize patients with combined systolic-diastolic hypertension to renal denervation or a placebo procedure. Both studies allow renal denervation treatments in renal artery branches and accessories. These studies will inform the design of the second pivotal phase of the program, which will more definitively analyze the antihypertensive effect of renal denervation.

At The Mount Sinai Hospital, we are one of the pioneer institutes in the country (the only one in the tristate area) providing this option with excellent safety and durability records. This procedure is carried out as a one-day procedure and, in some cases, patients can go home on the same day.

Reference:
A controlled trial of renal denervation for resistant hypertension: SYMPLICITY HTN-3 Trial. N Engl J Med 2014; 370; 1393-
Peripheral artery disease (PAD) most commonly affects the lower extremities, the result of atherosclerotic plaque in the vasculature leading to peripheral artery obstruction. The clinical manifestations, including claudication, rest pain, and ischemic ulceration of PAD, are due to lack of blood flow to the musculature relative to its metabolism, which results in pain in the affected muscle groups.

Lower extremity intermittent claudication is defined as a reproducible discomfort of a defined group of muscles that is induced by exercise and relieved with rest. Although the supply of blood may be adequate to meet the demands of an inactive muscle, a mismatch develops between the supply of blood and increased demand induced by activity, resulting in symptoms such as lower extremity discomfort or tightness with exertion. Atypical symptoms can also occur, such as non-specific pain, numbness, aching, or heaviness in the leg muscles.

Although lower extremity occlusive arterial disease can occur in a variety of segments, including aortoiliac, common femoral, superficial femoral, popliteal, tibial, and peroneal arteries, the femoropopliteal segment is an important target of therapy to alleviate symptoms. An endovascular treatment strategy for symptomatic atherosclerotic PAD has gained widespread acceptance and is now recommended as the primary revascularization strategy in these patients.

Percutaneous transluminal angioplasty (PTA) of the superficial femoral and popliteal artery has a high initial success rate, however restenosis can occur in 50 to 60 percent of cases. Additionally, randomized trials have demonstrated that bare-metal stents and drug-eluting stents implanted in these segments have excellent one-year primary patency rates of 70 to 80 percent. However, due to the dynamic stresses applied by the superficial femoral and popliteal artery, there may be a risk of stent fracture, or in-stent restenosis/thrombosis. Given these limitations of PTA and stenting, there has been a continued desire to develop new technologies with excellent long-term outcomes and without the need for leaving a permanent metallic implant.

Lately, the advent of drug-coated balloons (DCB) has significantly advanced therapy for the femoropopliteal segment. Drug-coated balloons provide a combination of balloon dilatation with local delivery of an antiproliferative drug, specifically paclitaxel, to optimally provide luminal gain and prevent restenosis, without leaving a permanent metallic scaffold. Randomized trials evaluating this novel therapy have been extremely promising, with superior primary patency rates and decreased need for target lesion revascularization compared to PTA. There are currently two DCBs on the market in the United States, Lutonix and IN.PACT Admiral. Additional next-generation DCBs, such as the Stellarex drug-coated balloon, have also been developed and are currently in clinical trials, with initial studies showing very optimistic results.

The IN.PACT SFA trial was a prospective, multicenter, randomized trial, comparing paclitaxel-coated DCB (IN.PACT Admiral) with PTA for treatment of symptomatic superficial femoral and popliteal artery disease. The trial enrolled 331 patients who were randomly assigned in a 2:1 ratio to treatment with DCB or PTA. The primary efficacy endpoint was primary patency, which was defined as freedom from restenosis or clinically driven target lesion revascularization. The trial revealed significantly higher primary patency at one- and two-year follow-up for drug-coated balloon therapy compared with plain balloon angioplasty (one year: 82.2 percent versus 52.4 percent; two year: 78.9 percent versus 50.1 percent).
percent). The trial also revealed significantly lower rates of clinically-driven target lesion revascularization at one- and two-year follow-up for drug-coated balloon therapy compared with plain balloon angioplasty (one year: 2.4 percent versus 20.6 percent; two year: 9.0 percent versus 27.8 percent). The IN.PACT SFA trial recently released its three-year outcomes, data which was presented at the Vascular Interventional Advances (VIVA) conference by Prakash Krishnan, MD of the The Mount Sinai Hospital on behalf of the IN.PACT SFA investigators in October 2016. These findings continued to reveal superior outcomes for the DCB-treated group compared to the PTA-treated group (primary patency at three years: 69.5 percent versus 45.1 percent; clinically driven TLR at three years: 15.5 percent versus 29.6 percent). Although there were no significant differences in the improvement from baseline quality of life between the two groups, or differences in improvement in walking distance, many more patients undergoing PTA required additional procedures to achieve these results.

Based on these studies, it is clearly evident that drug-coated balloon therapy has significantly changed the landscape in the treatment of femoropopliteal disease. This innovative technology has shown significantly improved primary patency rates and lower need for clinically-driven target lesion revascularization compared to PTA. Additionally, it provides an attractive alternative to stents as it provides an opportunity to avoid leaving a metallic implant inside the vessel and thus avoid risks associated with stents such as stent fracture, in-stent restenosis/thrombosis. Drug-coated balloon therapy stands to become a very important advancement and treatment option for patient with superficial femoral and popliteal artery disease in the future.

Reference:
Drug-coated balloon versus standard percutaneous transluminal angioplasty for the treatment of superficial femoral and/or popliteal peripheral artery disease: 12 month results for the IN.PACT SFA randomized trial. Circulation 2016 DOE 10.1161,20.

PATIENT: Natale Lattanzi, 64-year-old male
DIAGNOSIS: Bilateral PAD
TREATMENT: Complex PTA with atherectomy and drug coated balloon

“I know that I’m in the best hands—no doubt about it.”

“Before I found Dr. Krishnan, I was not doing too well at all. The poor blood flow in my extremities was causing parts of my leg and foot to turn black. When I went to my regular cardiologist for a check-up, they suggested treatment with a balloon and stents in their office. But when they started the procedure, they hit a blocked clot and I had to be rushed to the hospital. Thankfully, the clot passed and I survived. An endocrinologist at the hospital recommended that I see Dr. Krishnan. While everyone else wanted to amputate, Dr. Krishnan said, ‘Not yet!’ He was able to place a stent that got my blood moving again and he saved my leg and foot. No matter where Dr. Krishnan is, he’ll always be my doctor. I have very little pain now and, while I’ll never walk like I used to, I can’t complain because I still have my foot. I make regular visits to Dr. Krishnan so that they can keep things moving and listen to how my veins are working. Even when my insurance wouldn’t cover monthly visits, it was no matter to him—he still said to come in. He really knows what’s going on, and it’s impressive that he always knows about research being done all over the world. They are on top of things, thank God for that, and I know that I’m in the best hands—no doubt about it.”
Diabetes mellitus (DM) is associated with accelerated atherothrombosis, and as a result, patients with diabetes mellitus have a significantly increased risk of developing atherosclerotic cardiovascular disease compared to patients without DM. This excess risk is attributable to many factors, which include a greater amount of atheromatous plaque burden in the coronary arteries but also an increased platelet effect. Platelets play a pivotal role in the atherothrombotic complications observed in patients with acute coronary syndromes (ACS). Antiplatelet medications such as clopidogrel and aspirin have been the cornerstone in treatment for patients with cardiovascular events and particularly in patients who undergo coronary stent procedures. Typically after a patient undergoes a coronary stent procedure, an antiplatelet medication like clopidogrel is used to help protect against platelet thrombosis during the critical period the stent undergoes “healing.” Studies have demonstrated that patients with diabetes mellitus have an impaired response to clopidogrel therapy compared to non-diabetic patients—a term called “high on-treatment platelet reactivity” (HPR). HPR has been clearly identified as a major contributor to the high level of cardiovascular events, including stent thrombosis, in DM patients undergoing PCI.

Thankfully, newer, more potent antiplatelet medications, including ticagrelor, have been discovered and rigorously tested in large clinical trials and have a more rapid onset of action and a more predictable and robust antiplatelet effect compared to clopidogrel. The medications have been shown in large clinical trials to benefit patients undergoing coronary stenting especially in the setting of an acute coronary syndrome (heart attack). Studies have confirmed that compared with non-DM patients, DM patients who receive a coronary stent for treatment of an ACS tended to have a greater reduction in ischemic events after receiving prasugrel or ticagrelor, due to their greater antiplatelet effect. As a result, most patients with diabetes mellitus that present to the Cardiac Catheterization Laboratory with a heart attack will receive either ticagrelor or prasugrel in addition to aspirin after a coronary stent procedure.

Reference:
Percutaneous coronary intervention (PCI) with stenting, in conjunction with medications, has remained the preferred treatment for symptomatic obstructive coronary artery disease (CAD) for decades. Originally performed through larger arteries including the femoral artery in the groin and the brachial artery in the upper arm, pioneers in the field of interventional cardiology in the late 1990s and early 2000s demonstrated the feasibility of conducting the procedure through the radial artery, a smaller artery in the wrist.

Utilizing the radial artery for coronary procedures resulted in less procedure-related bleeding and vascular complications, with the additional benefit of reduced clinical events, such as heart attacks and death. One such important trial was the MATRIX (Minimizing adverse hemorrhagic events by transradial access site and systemic implementation of Angiomax) study which compared radial versus femoral access in patients with ACS (acute coronary syndrome) including STEMI (ST segment elevation myocardial infarction) heart attacks. This pivotal trial demonstrated a significant reduction in major cardiovascular events and bleeding in the radial group. A meta-analysis showed that, specifically in the group of ACS patients, radial access resulted in a 28 percent reduction in all-cause mortality.

Despite these data, only one in three patients in the United States undergoes PCI via the wrist, for a number of possible reasons. One such factor is in some individuals, the radial artery is too small or tortuous to accommodate the procedure. In these patients, experience is growing in using the ulnar artery, a different artery in the wrist, which is believed to provide the same clinical benefits. A recent meta-analysis of trials evaluating transulnar versus transradial access demonstrated similar safety and efficacy. As a result of this data, utilization of the ulnar artery in cases where the radial artery is unsuitable has become the norm at The Mount Sinai Hospital.

Cumulative data regarding the other important benefits of transradial and transulnar coronary interventions continues to mount as well. In addition to the improvements in clinical end points, evaluations of patient’s experience with the transradial/transulnar procedures compared with transfemoral procedures have consistently demonstrated a strong preference toward using the wrist for catheter entry. Earlier ambulation and earlier discharge from the hospital have been the main drivers of this preference. Additionally, due to the near absence of bleeding and vascular complications using this technique and the shorter time patients spend in the hospital, procedural costs, which are ultimately felt by the population in general, are greatly reduced by this technique as well.

As is the case in many aspects of cardiovascular care, The Mount Sinai Hospital continues to be a local and national leader in the area of transradial and transulnar procedures.

References:
1. Radial versus femoral access in patients with acute coronary syndromes undergoing invasive management: a randomized multicentre trial. Lancet. 2015; 385:2465-76

Key Points
- The radial artery has showed promise as an access site since the late 1990s, promising fewer complications and faster ambulation.
- Although the benefits of radial artery access have been demonstrated, only one in three cases in the United States utilizes the approach, in part due to patient physiology limiting access.
- The ulnar artery, also in the wrist, offers an alternative with similar benefits to radial artery access.
- The Mount Sinai Hospital is a leader in adopting radial and ulnar approaches to PCI.
Linking Genetics to Coronary Artery Disease

Jason C. Kovacic, MD, PhD

The factors that cause coronary artery disease (CAD) are among some of the most complex of any disease suffered by humankind. Risk factors such as smoking, diet, lack of exercise, and diabetes have long been appreciated as major risk factors that contribute to CAD. Importantly, while a genetic contribution to CAD has been known for many years, it is seldom appreciated that genetic factors may account for up to 50 percent of the likelihood of developing clinical CAD with symptoms such as angina or myocardial infarction. However, until very recently, our understanding of these genetic causes for CAD has been extremely limited. Indeed, this lack of proper understanding about the genetic contributions that cause CAD is so critical, that the phrase "missing heritability" has been used—to denote the fact that a large component of the cause of CAD is likely genetic, yet the specific mechanisms of this heritability are not well known.

In response to this major knowledge gap about the genetic contributions to CAD, we at the Mount Sinai Catheterization Laboratory, along with many top-level researchers and scientists around the world, have been conducting intensive studies to try and better understand these genetic causes of CAD. Among several of the major initiatives we are involved with is the YELLOW II study led by Annapoorna S. Kini, MD, which included a specific component focused on understanding changes in CAD plaque morphology that occur with intensive cholesterol lowering at the genetic level.

In other studies, Jason C. Kovacic, MD is an investigator in the landmark STARNET study. There is an extremely complex biologic and genetic interplay that occurs to cause CAD, heart attack and stroke. Therefore, risk factors such as diabetes and smoking do not work in isolation, but they have multiple effects and interactions that arise together with many added genetic factors and interactions, which ultimately cause CAD.
Triple Therapy Post DES

Roxana Mehran, MD  Jaya Chandrasekhar, MD

The 2013 American College of Cardiology/American Heart Association guidelines recommend the use of clopidogrel concurrently with oral anticoagulation medications for patients with non-valvular atrial fibrillation (AF) undergoing PCI, based on the findings of the WOEST trial.

However, with ever-improving stent technologies and availability of newer therapies, the optimal antithrombotic combination in these patients remains uncertain. Patients with AF-PCI are a complex and high-risk group prone to both ischemic and bleeding adverse events for prevention of stent thrombosis as well as prophylaxis against stroke. Several combinations of therapies may be employed in the treatment of these patients, including conventional anticoagulation with vitamin K antagonists (VKA) such as warfarin, or non-vitamin K antagonists (NOAC) such as rivaroxaban (Xarelto), apixaban (Eliquis), edoxaban (Savaysa) and dabigatran (Pradaxa). The recently presented PIONEER AF trial showed that AF-PCI patients treated with either low-dose rivaroxaban and P2Y12 therapy for 12 months or very low-dose rivaroxaban and dual antiplatelet therapy for one, six, or 12 months had a lower risk of clinically significant bleeding with equivalent ischemic outcomes compared to patients treated with triple therapy with VKA for one, six, or 12 months. Furthermore, patients on rivaroxaban also had lower rate of recurrent adverse event related hospitalizations.

How are physicians making these medication choices in the real world?

Although validated risk scores are available for assessment of stroke (CHADS2 and CHA2DS2-VASc) and bleeding risk (HAS-BLED and ATRIA), it is unclear how often these scores are used in practice and whether there is agreement between subjective physician assessments. In addition to physician assessment, patient perspectives and expected adherence might also play an important role in prescription choices, though this has not been formally examined in this group of subjects.

At The Mount Sinai Hospital, we designed and are conducting the ongoing AVIATOR 2 multicenter prospective registry to address these questions. In tune with the digital age of healthcare research, this study utilizes a smartphone application (Health Promise Survey) for point-of-care collection of physician and patient perspectives using a pre-specified study questionnaire. Clinical endpoints will include death, non-fatal myocardial infarction, stroke, stent thrombosis, target lesion revascularization, and major bleeding. These studies will provide much needed data for the impact of specific strategies in a growing AF-PCI patient population, facilitating a change in existing paradigms. This year, The Mount Sinai Hospital will again be at the forefront of research in the antithrombotic arena, coordinating the most anticipated trials and producing new evidence in the treatment of AF-PCI.

Reference:

PIONEER AF-PCI Trial
Bleeding Safety and Efficacy Endpoint

<table>
<thead>
<tr>
<th>Medication Combination</th>
<th>Clinically Significant Bleeding</th>
<th>Major Adverse Cardiac Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xarelto (15mg) + Plavix (75mg)</td>
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<td>7%</td>
</tr>
<tr>
<td>Xarelto (2.5mg BID) + DAPT</td>
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<td>0%</td>
</tr>
<tr>
<td>Coumadin + DAPT</td>
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Key Points

• Critical limb ischemia is an advanced stage of peripheral vascular disease that can present with resting pain, ulcer, or gangrene.

• Timely management of the disease can have a positive impact on long-term morbidity and mortality.

• The latest technology at Mount Sinai allows patients with critical limb ischemia to be treated by minimally invasive procedures with excellent outcomes.

Critical Limb Salvage Procedures

Vishal Kapur, MD  Prakash Krishnan, MD

Critical limb ischemia (CLI) is an advanced form of peripheral artery disease that is characterized by severe blockages of the arteries in the lower extremities. These blockages cause a marked reduction in blood flow to the legs and feet, resulting in resting pain and/or numbness. In advanced cases, patients may have skin breakdown, ulceration, and signs and symptoms of gangrene such as loss of sensation and muscle power, or cold legs. Patients at high risk include diabetics, smokers, and those with a history of heart disease and high blood pressure and cholesterol.

Approximately 1 to 3 percent of patients with PAD may present with CLI; however, with increasing life expectancy and the prevalence of diabetes, obesity, and sedentary lifestyles, these estimates are likely to increase. A published analysis by The Sage Group concluded that an estimated two million people in the United States have CLI, including undiagnosed patients. With the increasing prevalence of diabetes, there could be more than 3.5 million cases by 2020. CLI can reduce functional capacity and quality of life for affected patients when symptomatic, and in its most severe form, it is a major cause of limb amputation. In addition, this subgroup of patients is at an increased risk for myocardial infarction (MI), stroke, cancer, and death. The five-year mortality rate for patients with this condition is as high as 60 percent, with coronary events and strokes accounting for at least 70 percent of deaths in this population. Given this substantial health burden, CLI is the focus of evolving medical, endovascular, and surgical therapies aimed at improving the limb manifestations of the disease.

The principal goal in the management of these high-risk patients is early assessment and aggressive revascularization for preventing the progression of disease. At The Mount Sinai Hospital, our team of world-renowned interventional cardiologists is trained to manage these patients with utmost competency and professionalism. We are equipped to perform comprehensive diagnostic workups that include ankle-brachial index (ABI), duplex ultrasound, and angiography to evaluate the blockage and measure blood flow in the affected vessel. Depending on the location and extent of the blockage, we may perform one or more interventional procedures, such as balloon angioplasty, stent placement, and laser or rotational atherectomy to remove the blockages and restore normal blood flow. As a part of multidisciplinary approach, we partner with wound-care management, infectious diseases, and vascular surgery and work in close association to provide comprehensive care. We are also the world leaders in development and use of the latest technology. We were the first in the United States to use a drug-coated balloon as a part of treatment strategy. We are also extensively involved with research, including trials and publications at both national and international levels.

Reference:

Innovations in Heart Failure: Lifelong Support With a New Implantable Continuous Flow Pump

Sean Pinney, MD

Despite the success of percutaneous revascularization, some heart attack survivors develop the clinical syndrome of heart failure. These patients experience a high-symptom burden of shortness of breath and congestion, are hospitalized frequently and face a risk of shortened survival. Heart transplantation has been the therapy of choice for patients with end-stage heart failure, but a limited donor pool and restricted access to organs limits the wide application of this life-saving therapy.

Over the past 10 years, continuous flow left ventricular assist devices (LVADs) have emerged as a way to fill this gap between the need for lifelong therapies and the lack of sufficient availability of heart transplants. These small, durable blood pumps are surgically implanted and can generate enough blood flow to fully support the circulation at rest and with exercise. Patients supported with these pumps have experienced longer survival and improved quality of life compared with those receiving first-generation pumps, but an unacceptably high adverse-event burden persists. Although survival rates exceed 80 percent at one year, it has been estimated that only 30 to 40 percent of patients will be alive without experiencing a major adverse event such as bleeding, infection, stroke, or pump thrombosis (clotting).

The HeartMate 3™ is a next-generation LVAD that was designed to be more biocompatible and reduce adverse events. The pump consists of a single rotating disk that is suspended within an electromagnetic field and encased in a housing with wide gaps between the blades and the walls. These engineered features create a frictionless surface and reduce the shearing forces imparted to the blood as it passes through the pump.

Doctors at The Mount Sinai Hospital participated in the MOMENTUM-3 clinical trial to determine whether the HeartMate 3 pump was as good as, or better than, the currently approved HeartMate II® LVAD. The primary outcome—patient survival free of major stroke or urgent pump exchange—was similar for both pumps, but there were no instances of pump thrombosis for recipients of the HeartMate 3. This apparent elimination of a major adverse event offers hope to patients receiving LVADs for long-term or lifelong support.

The team at The Mount Sinai Hospital implanted 12 HeartMate 3 pumps in 2016 and is currently using the pump as part of a continuous access protocol associated with the MOMENTUM-3 trial. Led by site investigator and Surgical Director of the Mechanical Circulatory Support Program, Anelechi Anyanwu, MD, Mount Sinai was recognized as one of the top enrollers in this landmark clinical trial. Sean Pinney, MD, Director of Heart Failure and Transplantation for The Mount Sinai Health System, co-chaired the medical management committee that standardized the post-implant care of these complex patients. Together, Mount Sinai’s team of specialists helped advance the field of mechanical circulatory support to benefit patients with advanced heart failure.

Reference:

Key Points

- Even after surviving acute MI, some patients will develop heart failure.
- The gold standard of treatment for HF patients is transplantation, but the limited availability of donor organs remains an issue.
- Ventricular support devices emerged as a way to fill this gap, but carry a burden of adverse events post-implantation.
- Mount Sinai is studying the next generation of these devices, which may eliminate the burden of pump thrombosis.
Proven Risk Reduction with Patent Foramen Ovale (PFO) Closure in Cryptogenic Stroke

Barry A. Love, MD

It has been known for decades that patients with cryptogenic stroke are more likely to have a PFO (approximately 50 percent) than patients who have never experienced a stroke (20 to 30 percent). It is postulated that the mechanism of these strokes is due to paradoxical embolization of venous debris. Patients who have experienced a stroke and have a PFO are more likely to have recurrent stroke, and the best treatment strategy—medical therapy versus transcatheter closure of the PFO—has been a matter of debate. In November 2016, the follow-up results of the RESPECT trial, which randomized over 900 patients with cryptogenic stroke and a PFO to either medical therapy or PFO closure with the Amplatzer PFO occlude, were presented. Over a mean 5.6 years of follow-up, there was a 45 percent risk reduction (p=0.046) in the number of strokes in the device arm compared with the medically treated group. Based on this data, the FDA approved the Amplatzer PFO Occluder for treatment of patients with cryptogenic stroke and PFO. The FDA approval is worded as follows:

The AMPLATZER™ PFO Occluder is indicated for percutaneous transcatheter closure of a patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke.

On November 7, 2016, Barry A. Love, MD at The Mount Sinai Hospital performed the first-in-the-nation FDA approved PFO closure on a 46-year-old woman who had suffered a cryptogenic stroke. The 20-minute procedure is performed under light sedation and local anesthesia using a combination of fluoroscopy and intracardiac echocardiography to guide the placement of the occluder. Patients are usually discharged the same or next day on a single antiplatelet agent. Mount Sinai Heart continues to see an increasing number of patient referrals for PFO closure now that the procedure is FDA approved.

References:
2. PFO: “Please figure out” or now ‘potentially figured out?’ J Am Coll Cardiol. 2016 Mar 1;67(8):918-20
The Cardiac Catheterization Laboratory at The Mount Sinai Hospital is one of the safest labs in the country. Its outcomes are a testament to our multidisciplinary approach to patients with CAD. Mount Sinai Heart has ambulatory care centers and affiliated offices across New York City and the surrounding areas. Each year, providers refer more than 3,000 patients to us for catheterization. The key to our success in the lab comes from our rigorous pre-procedure and post-procedure ambulatory care protocols. Cardiologists in our ambulatory care network work in close collaboration with interventionalists to create individualized care pathways for our patients before they even step into the lab.

All patients referred for angiography are given the opportunity to see a Mount Sinai Heart physician. During that visit, we review diagnostic testing, appropriateness criteria, and decide on access and whether any special equipment or treatments are needed. Medications are reviewed, and we explain the risks and benefits of the procedure to the patient, and consent is often obtained. By thoroughly evaluating patients before they come to The Mount Sinai Hospital, we can plan to efficiently and safely perform more than sixty procedures a day.

The last published data of 2013 for risk-adjusted readmission rate in New York State revealed that 30-day readmission after PCI was 8.9 percent for The Mount Sinai Hospital, which is significantly lower than state wide average of approximately 11 percent. This is possible because of the multiple touch points and visits we have with patients post-discharge.

After the procedure, all patients are given a follow-up appointment within two weeks to assess their progress. During that visit, we ascertain if they are compliant with antiplatelet medications and if further testing or intervention is needed. To evaluate any urgent post-procedure issues, we offer our patients walk-in service from 7 am to 9 pm in our ambulatory area. This service helps patients avoid the ER for many issues. Even though we always transition our patients back to their referring providers, our outreach staff continues to touch base with the patients to assist with any issues and answer questions the patients may have.

Improving Ambulatory Interventional Care

Jeffrey Bander, MD

Key Points

• The Cardiac Catheterization Laboratory at The Mount Sinai Hospital is one of the safest labs in the country.

• Despite a high volume of procedures, our adherence to standardized, patient-centered protocols helps us deliver consistent outcomes to a diverse patient population.

• Part of that approach involves including patients and their providers in a team approach that provides education and support to ensure patient safety and compliance.
**Publications**

**Top Ten Major Publications of 2016**

1. **Intracoronary Imaging, Cholesterol Efflux, and Transcriptomes After Intensive Statin Treatment: The YELLOW II study.**


*Journal of the American College of Cardiology.* Oct 2016, 23134; DOI: 10.1016/j.jacc.2016.10.029

**Clinical Implication:** The study demonstrated an independent association between fibrous cap thickening and improved CEC that may contribute to morphological changes suggesting plaque stabilization among patients taking intensive statin therapy. Furthermore, the significant perturbations in PBMC transcriptome may help determine the beneficial effects of statin on plaque stabilization.

2. **Assessment of Fibrous Cap Thickness by Optical Coherence Tomography in Vivo: Reproducibility and Standardization.**

Annapoorna S. Kini, Yuliya Vengrenyuk, Takahiro Yoshimura, Mitsuaki Matsumura, Jacobo Pena, Usman Baber, Pedro Moreno, Roxana Mehran, Jason C. Kovacic, Usman Baber, Joel T. Dudley, Jagat Narula, Samin Sharma

*Journal of the American College of Cardiology.* Oct 2016, 23133; DOI: 10.1016/j.jacc.2016.10.028

**Clinical Implication:** Careful consideration of OCT features mimicking fibroatheroma lesions and imaging artifacts contributed to significantly higher levels of interobserver agreement. Interobserver variation can be partially resolved by development of standard interpretation algorithms as shown in this state-of-the-art manuscript.

3. **Everolimus-Eluting Stents or Bypass Surgery for Left Main Coronary Artery Disease.**

Gregg W. Stone, MD, Joseph F. Sabik, MD, Patrick W. Serruys, MD, Ph.D., Charles A. Simonton, MD, Philippe Généreux, MD, John Puskas, MD, David E. Kandzari, MD, Marie-Claude Morice, MD, Nicholas Lembo, MD, W. Morris Brown, III, MD, David P. Taggart, MD, Adrian Banning, MD, Béla Merkely, MD, Ferenc Horkay, MD, Piet W. Boonstra, MD, Ad J. van Boven, MD, Imre Ungi, MD, Gabor Bogáts, MD, Samer Mansour, MD, Nicolas Noiex, MD, Manel Sabaté, MD, José Pomar, MD, Mark Hickey, MD, Anthony Gershlick, MD, Pawel Buszman, MD, Andrzej Bochenek, MD, Erick Schampaert, MD, Pierre Pagé, MD, Ovidiu Dressler, MD, Ioanna Kosmidou, MD, Roxana Mehran, MD, Stuart J. Pocock, Phd, and A. Pieter Kappetein, MD


**Clinical Implication:** In patients with left main coronary artery disease and low or intermediate SYNTAX scores by site assessment, PCI with everolimus-eluting stents was noninferior to CABG with respect to the rate of the composite end point of death, stroke, or myocardial infarction at three years.

4. **Plaque morphology predictors of side branch occlusion after provisional stenting in coronary bifurcation lesion: Results of optical coherence tomography bifurcation study (ORBID).**

Annapoorna S. Kini, MD, Yuliya Vengrenyuk, PhD, Jacobo Pena, MD, Takahiro Yoshimura MD, Sadik R. Panwar MD, Sadao Motoyama MD, PhD, Safwan Kezbor MD, Choudhury M. Hasan MD, Sameet Palkhiwala MD, Jason C. Kovacic MD, PhD, Pedro Moreno MD, Usman Baber MD, Roxana Mehran MD, Jagat Narula MD, PhD, Samin K. Sharma, MD

*Catheterization and Cardiovascular Interventions.* Mar 2016, 89:259-268; DOI: 10.1002/ccd.26524

**Clinical Implication:** High lipid content of the main vessel lesion and a contralateral location of lipid in the bifurcation area may contribute to side branch stenosis after provisional stenting.
5. Neurological Outcomes With Embolic Protection Devices in Patients Undergoing Transcatheter Aortic Valve Replacement: A Systematic Review and Meta-Analysis of Randomized Controlled Trials.

Gennaro Giustino, MD, Roxana Mehran, MD, Roland Veltkamp, MD, Michela Faggioni, MD, Usman Baber MD, George D. Dangas, MD


Clinical Implication: Use of embolic protection devices seems to be associated with reductions in imaging markers of cerebral infarction and showed early clinical neurological effectiveness in patients undergoing TAVR.

6. Predicting Risk of Ischemic or Bleeding Events After Percutaneous Coronary Intervention.

Roxana Mehran, MD, Usman Baber MD


Clinical Implication: Among patients not sustaining major bleeding or ischemic events one year after PCI, a prediction rule assessing late ischemic and bleeding risks to inform dual antiplatelet therapy duration showed modest accuracy in derivation and validation cohorts. This rule requires further prospective evaluation to assess potential effects on patient care, as well as validation in other cohorts.

7. Prevention of Bleeding in Patients with Atrial Fibrillation Undergoing PCI.

C. Michael Gibson, MD, Roxana Mehran, MD, Christoph Bode, MD, Jonathan Halperin, MD, Freerk W. Verheugt, MD, Peter Wildgoose, PhD, Mary Birmingham, PharmD, Juliana Ianus, PhD, Paul Burton, MD, PhD, Martin van Eckels, MD, Serge Korjian, MD, Yazan Daaboul, MD, Gregory Y.H. Lip, MD, Marc Cohen, MD, Steen Husted, MD, Eric D. Peterson, MD, MPH, and Keith A. Fox, MB, ChB


Clinical Implication: In participants with atrial fibrillation undergoing PCI with placement of stents, the administration of either low-dose rivaroxaban plus a P2Y12 inhibitor for 12 months or very-low-dose rivaroxaban plus DAPT for 12 months was associated with a lower rate of clinically significant bleeding than was standard therapy with a vitamin K antagonist plus DAPT for 12 months.

8. Intravascular Ultrasound Is an Effective Tool for Predicting Histopathology-Confirmed Evidence of Adventitial Injury Following Directional Atherectomy for the Treatment of Peripheral Artery Disease.

Prakash Krishnan, MD, Arthur Tarricone, MPH, Ziad Ali, MD, K-Raman Purushothaman, MD, Jessica Overbey, MS, Miguel Vasquez, MD, Jose Wiley, MD, Vishal Kapur, MD, Karthik Guja, MD, Richard T. Atallah, Katarzyna Nasiadko, MD, Annapoorna Kini, MD, Samin Sharma, MD


Clinical Implication: The use of adjunctive IVUS with angioplasty and stenting has been shown to increase patency rates for complex TASC II A-C4 and iliac lesions.

9. Endothelial to mesenchymal transition (EndMT) is common in atherosclerotic lesions and is associated with plaque instability.


Nature Communications. Jun 2016, 7:11853; DOI 10.1038/ncomms11853

Clinical Implication: This study has shown that phenotypic cell switching by EndMT is a major additional feature of atherosclerosis, with EndMT potentially driving this disease by altering collagen-MMP balance. Humans EndMT is more common in complex lesions and ruptured plaques underscoring the clinical importance of this process.

10. Multimodality Intravascular Imaging to Evaluate Sex Differences in Plaque Morphology in Stable CAD.

Aditya S. Bharadwaj, Yuliya Vengrenyuk, Takahiro Yoshimura, Usman Baber, Choudhury Hasan, Jagat Narula, Samin K. Sharma, Annapoorna S. Kini

JACC: Cardiovascular Imaging. Apr 2016, 9(4):400-407; DOI: 10.1016/j.jcmg.2016.02.007

Clinical Implication: Among men and women with stable CAD referred for coronary angiography, there was no difference in plaque characteristics as assessed by multimodality imaging. These findings, which are hypothesis generating, suggest that equally aggressive primary and secondary preventive efforts irrespective of sex must be undertaken.
**Research and Clinical Trials**

- There are more than 60 research trials going on in the Cardiac Catheterization Laboratory at Mount Sinai Hospital.
- Our Catheterization Laboratory is among the top enrolers for many of the research trials in the United States.
- Results of these trials have resulted in advancement of the field of interventional cardiology and FDA approval of many new devices.

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Study Details</th>
<th>Sponsor</th>
<th>Principal Investigator(s)</th>
<th>Target Enrollment and Study Sites</th>
<th>Current Status/Enrollment at MSH</th>
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</thead>
<tbody>
<tr>
<td>COAPT Trial</td>
<td>The purpose of the Cardiovascular Outcomes Assessment of the MitraClip® Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation (COAPT) Trial is to confirm the safety and effectiveness of the MitraClip System for the treatment of moderate-to-severe or severe functional mitral regurgitation (FMR) in Symptomatic Heart Failure Subjects.</td>
<td>Abbott Vascular</td>
<td>S. Sharma</td>
<td>485 (USA) 52 Centers</td>
<td>Ongoing/4 subject enrolled</td>
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<tr>
<td>EVOLUT-R Low Risk TAVR Trial</td>
<td>Transcatheter aortic valve replacement (TAVR) in patients with severe, symptomatic Aortic Stenosis (AS) at low surgical risk by randomizing patients to either Surgical Aortic Valve Replacement (SAVR) or TAVR with the Medtronic CoreValve® System.</td>
<td>Medtronic Inc.</td>
<td>S. Sharma</td>
<td>1,200 (USA) 75 Centers</td>
<td>Ongoing/11 subjects enrolled</td>
</tr>
<tr>
<td>ISCHEMIA Trial</td>
<td>International Study of Comparative Health Effectiveness with Medical versus Invasive Approaches</td>
<td>NHLBI</td>
<td>J. Sweeney</td>
<td>8,000 (Global) 400 Centers</td>
<td>Ongoing/4 subjects enrolled</td>
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<td>GALILEO Trial</td>
<td>Global multicenter, open-label, randomized, event-driven, active-controlled study comparing rivaroxaban-based antithrombotic strategy to an antiplatelet-based strategy after transcatheter aortic valve replacement (TAVR) to optimize clinical outcomes.</td>
<td>Bayer Pharma AG</td>
<td>A. Kini</td>
<td>1,520 (Global) 65 Centers</td>
<td>Ongoing/21 subjects enrolled</td>
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<tr>
<td>Renal Guard Trial</td>
<td>A study to evaluate RenalGuard System Safety &amp; Efficiency When Compared With Standard Care in the Prevention of Contrast Induced Nephropathy (CIN) in the setting of a Catheterization Laboratory.</td>
<td>PLC Medical Systems</td>
<td>G. Dangas</td>
<td>326 (USA) 20 Centers</td>
<td>Ongoing/49 subjects enrolled</td>
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<tr>
<td>Study Title</td>
<td>Study Details</td>
<td>Sponsor</td>
<td>Principal Investigator(s)</td>
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<td>ORBID-OA Trial</td>
<td>Optical Coherence Tomography Predictors of Functionally Significant Side Branch Compromise after Orbital Atherectomy and Stenting of Main Vessel in Calcified Bifurcation Lesions.</td>
<td>Cardiovascular Systems Inc.</td>
<td>A. Kini</td>
<td>30 (USA) 1 Center</td>
<td>Ongoing/2 subjects enrolled</td>
</tr>
<tr>
<td>PARACHUTE IV Trial</td>
<td>Percutaneous Ventricular Restoration in Chronic Heart Failure due to Ischemic Heart Disease</td>
<td>CardioKinetix, Inc.</td>
<td>G. Dangas</td>
<td>200 (USA) 40 Centers</td>
<td>Ongoing/3 subjects enrolled</td>
</tr>
<tr>
<td>SHIELD II Trial</td>
<td>Supporting Patients Undergoing High-Risk PCI Using a High-Flow Percutaneous Left Ventricular Support Device</td>
<td>St. Jude Medical</td>
<td>S. Sharma</td>
<td>425 (USA) 10 Centers</td>
<td>Ongoing/20 subjects enrolled</td>
</tr>
<tr>
<td>SPYRAL HTN ON/OFF Study</td>
<td>Global Clinical Study of Renal Denervation with the Symplicity Spryaltm multi-electrode renal denervation system in Patients with Uncontrolled Hypertension in the Absence of Antihypertensive Medications</td>
<td>Medtronic Inc.</td>
<td>G. Dangas</td>
<td>220 (USA) 15 Centers</td>
<td>Ongoing/10 subjects enrolled</td>
</tr>
<tr>
<td>TWILIGHT Study</td>
<td>Ticagrelor with Aspirin or Ticagrelor Alone in High-Risk Patients After Coronary Intervention</td>
<td>AstraZeneca</td>
<td>S. Sharma</td>
<td>9000 (Global) 120 Centers</td>
<td>Ongoing/112 subjects enrolled</td>
</tr>
</tbody>
</table>
Samin K. Sharma, MD, FACC, FSCAI
Director, Clinical and Interventional Cardiology
President, Mount Sinai Heart Network
Dean of International Clinical Affiliations
Anandi Lal Sharma Professor of Medicine in Cardiology

Education and Training
• MBBS: SMS Medical College Jaipur, India
• Residency, Internal Medicine: NY Infirmary; Beekman Downtown Hospital, NY
• Fellowship, Cardiology: City Hospital Center at Elmhurst, NY
• Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Samin K. Sharma, MD is an interventional cardiology expert, well known for performing high risk complex coronary interventions with an extremely high success rate (>99 percent) while achieving an extremely low complication rate (<0.5 percent major complication). He has received the prestigious two star designation (significantly lower than expected mortality) numerous times by the New York State Department of Health and the Governor’s Award of Excellence in Medicine in 1996. He has served on New York State’s Cardiac Advisory Board since 2004. Under Dr. Sharma’s leadership, The Mount Sinai Hospital Cardiac Catheterization Laboratory has become one of the safest and busiest centers in New York, providing state-of-the-art cardiac and interventional care for all types of simple and complex heart patients. In addition to coronary interventions, Dr. Sharma specializes in the non-surgical treatment of mitral and aortic valve disease including transcatheter aortic valve replacement (TAVR) and MitraClip procedures (TMVR). He has been dubbed “master of Rotablator” and is regularly featured on national and local TV and in newspapers and magazine including Newsday, Newsweek, New York Times, New York Post, Forbes, Wall Street Journal, New York Daily News, Washington Post, New York Magazine, India Abroad, and India Today. He has received numerous awards: 2015 Honorary Master of Science PhD degree by Rajasthan University Jaipur India, 2014 Distinguished Physician Scientist by AAPI-QLI for excellence in Medicine, 2011 Ellis Island Medal of Honor, 2011 American Heart Association Achievement in Cardiovascular Science & Medicine Award, 2011 American Association of Physicians of Indian Origin (AAPI) Physician of the Year, 2010 Association of Indians in America (AIA) for excellence in Medicine, 2003-2007 and 2010-2015 Best Doctors by New York Magazine, 2008-2015 Super Doctors, 2007 Jacobi Medallion Award by The Mount Sinai Hospital, 2007 Physician of the Year by The Mount Sinai Hospital. He has authored over 210 papers and 13 book chapters in the field of coronary interventions, structural heart disease and safety of percutaneous interventions. He is also a philanthropist, and The Mount Sinai Hospital Cardiac Catheterization Laboratory is now named the Dr. Samin K. Sharma Family Foundation Cardiac Catheterization Laboratory. Dr. Sharma has built a 250-bed heart hospital (EHCO) in his native Jaipur, India to provide the best care to all patients irrespective of their financial and social status.
Annapoorna S. Kini, MD, MRCP, FACC
Director, Cardiac Catheterization Laboratory
Interventional Director, Structural Heart Program
Director, Interventional Cardiology Fellowship Program
Zena and Michael A Wiener Professor of Medicine, Cardiology

Education and Training
• MBBS: Kasturba Medical College Mangalore, India
• Residency, Medicine/Cardiology: University of Wales Cardiology, UK
• Fellowship, Cardiology: The Mount Sinai Hospital, NY
• Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Annapoorna Kini, MD performs over 1,000 coronary interventions annually (the highest number by a female interventionalist in the United States) with an extremely low complication rate of <0.3 percent. According to the New York State Department of Health Report for 2004-2006, 2005-2007, 2009-2011 and 2011-2013, Dr. Kini received the two star status for percutaneous coronary intervention (PCI) safety among >500 other interventionalists. She is highly regarded for performing complex coronary interventions, especially in chronic total occlusions for patients with advanced heart disease, with the utmost safety and excellent long-term results. She is also a national expert in various intracoronary imaging modalities such as optical coherence tomography and near-infrared spectroscopy. Dr. Kini also specializes in the noncoronary interventions of mitral and aortic balloon valvuloplasty, alcohol septal ablation for obstructive hypertrophic cardiomyopathy, catheter-based aortic valve implantations (TAVR), and mitral valve therapies. As Director, she has taken a leadership role in enhancing the research programs of The Mount Sinai Cardiac Catheterization Laboratory. Several projects in coronary imaging are currently under way, including the YELLOW Trial and various YELLOW substudies. The most recent YELLOW II study was an ambitious translational combination of multi-modality imaging with clinically relevant cellular biology and comprehensive transcriptomics.

Dr. Kini is an excellent teacher, and is dedicated to the teaching of both cardiology and interventional fellows. She is the Director of the largest Interventional Fellowship Program. In fact, the 2012 batch of Mount Sinai interventional fellows created a teaching award in her name, “The Annapoorna S. Kini Fellows’ Choice Award” for excellence in teaching. She was the recipient of this award for several years. Dr. Kini is the Director of the Annual Live Symposium of Complex Coronary & Vascular Cases at The Mount Sinai Medical Center, one of the most attended and respected meetings in the field of interventional cardiology in the country. She is the Director of monthly live web casts and plays a key role in educating interventionalists globally in the technical aspects of complex coronary interventions via monthly webcasts on www.ccclivecases.org and www.structuralheartlivecases.org with a worldwide audience of several thousand physicians over 132 countries.

In 2011, Dr. Kini received the “Rock Star of Science” award from the American Heart Association. She is the recipient of 2011 Dean’s Award for Excellence in Clinical Medicine at the The Mount Sinai Hospital for unprecedented clinical skills. She was listed as a New York Times Magazine Super Doctor every year since 2009 and was awarded “The Physician of the Year” in 2014 by the nurses association of The Mount Sinai Hospital. She received the Excellence in Medicine Award by the National Association of Physicians of India (AAPI) in July 2016.
Prakash Krishnan, MD, FACC
Director of Endovascular Services, The Mount Sinai Health System
Associate Professor of Medicine (Cardiology)

Education and Training
• MBBS: Rajah Muthiah Medical College, Chidambaram, Tamil Nadu, India
• Residency, Internal Medicine: St. Vincent’s Medical Center of Richmond, New York, NY
• Fellowship, Cardiology: Ochsner Clinic Foundation, New Orleans, LA
• Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY
• Fellowship, Endovascular Intervention: North Central Heart Institute, Sioux Falls, SD

Prakash Krishnan, MD is a world-renowned expert in peripheral vascular disease and is internationally recognized as a leader in the catheter-based treatment of peripheral arterial disease. Dr. Krishnan’s expertise includes nonsurgical treatment of coronary and peripheral vascular diseases including coronary stents, peripheral vascular angioplasty and stents, atherectomy, carotid stents, renal stents, renal denervation, and complex venous disease intervention. Dr. Krishnan is a patient advocate and an educator. He has built a robust community-based outreach program that serves a vast population of patients with complex coronary and peripheral arterial diseases at offices in all five boroughs. He is the Director of the Endovascular Intervention Fellowship in the Cardiac Catheterization Laboratory and has been educating interventionalists globally via live satellite transmissions within national and international meetings and with the monthly webinar showcased at www.peripheralinterventions.org. He is the current Co-National Primary investigator in the ILLUMENATE Trial, a multicenter randomized control study evaluating the safety and efficacy of the Stellarex drug coated balloon in femoro-popliteal lesions. He has received numerous awards and honors, most recently the Reverend Dr. Martin Luther King Legacy Award for Physician Services from Clergy with a Purpose in 2016. He has authored numerous peer-reviewed articles and book chapters on peripheral arterial disease and is the Co-Director of the annual Live Symposium of Complex Coronary and Vascular Cases, an Icahn School of Medicine at Mount Sinai and Cardiovascular Institute-supported program, and Director of Mount Sinai’s Peripheral Interventions Live webinar.

George Dangas, MD, PhD, FACC, FSCAI
Director, Cardiovascular Innovation
Professor of Medicine (Cardiology)
Professor of Surgery (Vascular)

Education and Training
• MD, PhD: National Kapodistrian University of Athens, Greece
• DHM: Naval School of Hyperbaric Medicine, Hellenic Navy, Athens
• Residency, Internal Medicine: Miriam Hospital, Brown University, Providence, RI
• Fellowship, Cardiology: The Mount Sinai Hospital, NY
• Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

George Dangas, MD performs a wide spectrum of complex cardiovascular interventional procedures to treat coronary and valvular heart disease, aortic, carotid and peripheral arterial disease, and resistant hypertension. Dr. Dangas is a leading authority in the performance of nonsurgical cardiac and vascular interventions and in the development of innovative approaches to treat complex problems across many specialties. He is currently a trustee of the American College of Cardiology and Editor in Chief of CardioSource WorldNews Interventions, and has been chair of the Interventional Scientific Council and a Trustee of the Society for Cardiovascular Angiography & Interventions. He is co-director of the annual conferences “Transcatheter Cardiovascular Therapeutics” and “Interventional Fellows’ Courses” in the United States and Europe, and a key faculty and program committee member for multiple international conferences including the ACCi2 Summit, ACCIS, AHA, and SCAI for many years. Dr. Dangas is the Director of Academic Affairs at the Cardiovascular Research Foundation.
**Roxana Mehran, MD, FACC, FACP, FCCP, FESC, FAHA, FSCAI**
Director, Interventional Cardiovascular Research and Clinical Trials
Professor of Medicine (Evidence and Health Policy)

**Education and Training**
- MD: St. George’s University School of Medicine, Grenada, WI
- Residency, Internal Medicine: University of Connecticut
- Fellowship, Cardiovascular Disease: The Mount Sinai Hospital, NY
- Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Roxana Mehran, MD is internationally recognized for her work as a clinical trial specialist with complex data analyses. Her research interests expand from mechanisms of restenosis to treatment and prevention of acute kidney injury in cardiac patients, outcomes research, and advancing pharmacologic and interventional treatments for acute coronary syndromes and acute myocardial infarction. In addition to founding a highly regarded academic research organization at the Cardiovascular Research Foundation, she is a widely published author and is among the most sought-out speakers at national and international scientific conferences. She has served as course Co-director of the annual Transcatheter Cardiovascular Therapeutics (TCT) conference for the last 15 years. Dr. Mehran is a member of the editorial board of multiple peer-reviewed journals and has served on the Board of Trustees of SCAI, the program committee of the AHA Scientific Sessions, and the writing committee of the ACC/AHA PCI guidelines. She is a member of the Board of Directors for Harboring Hearts, and the program chair for the Society of Cardiac Angiography and Interventions Women in Innovations (SCAI-WIN) Initiative. Dr. Mehran is a practicing interventional cardiologist and is active in the teaching program of Cardiology at the Icahn School of Medicine at Mount Sinai.

**Joseph M. Sweeny, MD, FACC**
Medical Director, Ambulatory Cardiology Center
Assistant Professor of Medicine (Cardiology)

**Education and Training**
- MD: Georgetown University School of Medicine, Washington, DC
- Residency: Hospital of the University of Pennsylvania, Philadelphia, PA
- Fellowship, Cardiology: The Mount Sinai Hospital, NY
- Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Joseph Sweeny, MD performs both diagnostic cardiac catheterization and coronary interventions. He is the principal investigator of multiple national clinical trials and is actively involved in the interventional cardiology fellowship training program as the Associate Program Director. In 2014, he became the Medical Director of the Lauder Ambulatory Cardiology Center, which provides comprehensive ambulatory clinical care and all kinds of non-invasive cardiac testing in one central location. His research has focused mainly on the antiplatelet therapy in the treatment of acute coronary syndrome. He is the site principal investigator of an ongoing NIH sponsored Ischemia Trial.

**Clinical Interests:**
- Acute Myocardial Infarction
- Fellows Education
- Coronary Intervention

**Phone:** 212-241-7016
**Email:** joseph.sweeny@mountsinai.org

**Clinical Interests:**
- Restenosis Prevention
- Contrast-Induced Acute Kidney Injury (AKI)
- Cardiovascular Disease in Women

**Phone:** 212-659-9691
**Email:** roxana.mehran@mountsinai.org

**Clinical Interests:**
- Restenosis Prevention
- Contrast-Induced Acute Kidney Injury (AKI)
- Cardiovascular Disease in Women
FULL-TIME ATTENDINGS (LISTED ALPHABETICALLY)

Farah E. Atallah-Lajam, MD
Associate Clinical Professor of Medicine (Cardiology)

Education and Training
• MD: Universidad Autonoma De Santo Domingo, Santo Domingo
• Residency, Internal Medicine: Elmhurst Hospital
• Fellowship, Cardiology: Brooklyn Hospital Center
• Fellowship, Cardiac Catheterization, Nuclear Cardiology: Lenox Hill Hospital, NY

Clinical Interests: Clinical Cardiology, Cardiac Catheterization, Nuclear Cardiology
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Usman Baber, MD, MS
Assistant Professor of Medicine (Cardiology)

Education and Training
• MD: University of Texas Southwestern Medical Center, Dallas, TX
• MS: Columbia University, NY
• Residency, Internal Medicine: Parkland Memorial Hospital, Dallas, TX
• Fellowship, Cardiology: The Mount Sinai Hospital, NY
• Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Clinical Interests: Coronary Interventions, High-Risk Cardiac Populations, Cardiorenal Physiology
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Education and Training
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• Residency: Columbia Presbyterian Medical Center, NY
• Fellowship, Cardiology: The Mount Sinai Hospital, NY
• Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Clinical Interests: Clinical Cardiology, Cardiac Catheterization, Coronary Interventions
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Nitin Barman, MD
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Education and Training
• MD: University of Chicago
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• Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Clinical Interests: Clinical Cardiology, Transradial Intervention, AMI Intervention
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Srinivas Duvvuri, MD
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• MD: University of the West Indies Faculty of Medical Sciences
• Residency, Internal Medicine: Howard University
• Fellowship, Cardiovascular Disease: UMDNJ-New Jersey Medical School
• Fellowship, Cardiovascular Disease: Mount Sinai School of Medicine

Clinical Interests: General Cardiology, Cardiac Catheterization, Interventional Cardiology
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Lynne Glasser, MD
Director, Interventional Inpatient Service
Assistant Professor of Medicine (Cardiology)

Education and Training
• MD: SUNY Downstate Medical Center, NY
• Residency, Internal Medicine: New York University Medical Center
• Fellowship, Cardiology: Manhattan Veterans Administration Medical Center

Clinical Interests: Clinical Cardiology, Preventive Cardiology, Inpatient Cardiology
Since joining The Mount Sinai Hospital in November 2008, Dr. Glasser has been playing an important role in the treatment and management of interventional patients, before and after the procedure.
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Radha Gopalan, MD
Associate Professor of Medicine (Cardiology)

Education and Training
• MD: St. George’s University
• Residency, Internal Medicine: Beth Israel Medical Center (Newark)
• Fellowship, Cardiovascular Disease: Cooper Hospital-Univ. Med. Center
• Fellowship, Heart Failure & Cardiac Transplant: Hahnemann University Hospital
• Fellowship, Electrophysiology/Cardiology: Hahnemann University Hospital

Clinical Interests: Clinical Cardiology, Cardiac Catheterization, Heart Failure
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Vishal Kapur, MD, FACC, FSCAI, RPVI
Director of Endovascular Services, Mount Sinai St. Luke’s
Assistant Director, Endovascular Services, The Mount Sinai Hospital
Assistant Professor of Medicine (Cardiology)

Education and Training
• MD: University College of Medical Sciences, University of Delhi, India
• Residency: University of Texas Medical Branch
• Fellowship, Cardiology: Methodist DeBakey Heart & Vascular Center/UTMB, TX
• Fellowship, Interventional Cardiology: Columbia University Medical Center, NY
• Fellowship, Endovascular Medicine: Columbia University Medical Center, NY

Clinical Interests: Coronary Interventions, Peripheral Interventions, Non-Invasive Vascular Medicine
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Jagat Narula, MD, PhD
Director, Cardiovascular Imaging Program, Mount Sinai Health System
Chief of Cardiology, Mount Sinai St. Luke’s
Philip J. and Harriet L./uni00A0Goodhart/uni00A0Chair in Cardiology
Professor of Medicine & Radiology

Education and Training
• MD: SMS Medical School, India
• Fellowship [Cardiology, Heart Failure & Transplantation, Nuclear Cardiology]:
  Massachusetts General Hospital and Harvard Medical School
• Fellowship, Vascular Biology: National Heart Lung and Blood Institute, National Institutes of Health
• Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Clinical Interests: Noninvasive and Invasive Cardiovascular Imaging

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Jason Kovacic, MD, PhD
Associate Professor of Medicine (Cardiology)

Education and Training
• MD: University of Melbourne, Australia
• Fellowship, Internal Medicine: Prince of Wales Hospital, Sydney, Australia
• Fellowship, Cardiology: St. Vincent’s Hospital, Sydney, Australia
• Fellowship, Vascular Biology: National Heart Lung and Blood Institute, National Institutes of Health
• Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Clinical Interests: Atherosclerosis, Vascular Biology, Coronary Interventions

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Barry A. Love, MD, FSCAI
Director, Congenital Cardiac Catheterization Laboratory
Assistant Professor of Pediatrics and Medicine

Education and Training
• MD: University of Western Ontario
• Residency, Pediatrics: McGill University Medical Center
• Fellowship: Children’s Hospital Boston

Clinical Interests: Pediatric Catheterization and Intervention, Adult Congenital Heart Disease

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Pedro R. Moreno, MD, FACC
Director, Cardiac Catheterization Laboratory, Mount Sinai St. Luke’s
Professor of Medicine (Cardiology)

Education and Training
• MBBS: Universidad Javeriana, Bogota
• Residency, Internal Medicine: Brigham and Women’s Hospital
• Fellowship, Cardiology: Massachusetts General Hospital
• Fellowship, Interventional Cardiology: Massachusetts General Hospital

Clinical Interests: Coronary Artery Disease, Interventional Cardiology, Plaque Imaging

Phone: 212-241-3497  Email: pedro.moreno@mountsinai.org
Sameet Palkhiwala, MD
Director of Cardiology, Mount Sinai Queens
Assistant Clinical Professor of Medicine (Cardiology)

Education and Training
• MD: New York Medical College
• Residency, Internal Medicine: St. Luke’s-Roosevelt Medical Center
• Fellowship, Cardiology: St. Vincent’s Medical Center
• Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Clinical Interests: Clinical Cardiology, Endovascular Interventions, Coronary Interventions
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Sean P. Pinney, MD, FACC
Director, Advanced Heart Failure and Cardiac Transplant Program
Associate Professor of Medicine (Cardiology)

Education and Training
• MD: Georgetown University School of Medicine
• Residency, Internal Medicine: Beth Israel Deaconess Medical Center, Boston
• Fellowship, Cardiology: Columbia-Presbyterian Medical Center

Clinical Interests: Cardiac Catheterization, Cardiac Transplantation, Heart Failure
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William J. Schwartz, MD
Assistant Clinical Professor of Medicine (Cardiology)

Education and Training
• MD: Albert Einstein College of Medicine, NY
• Residency, Internal Medicine: Bronx Municipal Hospital Center
• Fellowship, Cardiology: Bronx Municipal Hospital Center
• Fellowship, Cardiac Catheterization: New York University Medical Center

Clinical Interests: Clinical Cardiology, Noninvasive Cardiology, Cardiac Catheterization
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Partho P. Sengupta, MD, FACC
Director, Interventional Echocardiography
Professor of Medicine (Cardiology)

Education and Training
• MD: Government Medical College, Nagpur, India
• Residency: Mayo Clinic, Rochester, MN
• Fellowship, Cardiology: Mayo Clinic, Scottsdale, AZ
• Fellowship, Advanced Fellowship in Echocardiography: Mayo Clinic, Rochester, MN

Clinical Interests: Structural Heart Imaging, Cardiac Muscle Mechanics; Automated Imaging Algorithms
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Joshua Shatzkes, MD  
Assistant Professor of Medicine (Cardiology)  

Education and Training  
• MD: SUNY Downstate Medical Center  
• Residency, Internal Medicine: Yale-New Haven Hospital  
• Fellowship, Cardiology: The Mount Sinai Hospital, NY  

Clinical Interests: Cardiovascular Disease, Noninvasive Imaging, Hypertension  

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Michael Alan G. Sicat, MD  
Assistant Professor of Medicine (Cardiology)  

Education and Training  
• MD: University of the East Ramon Magsaysay Memorial Med CTR, Quezon City, Philippines  
• Residency: Staten Island University Hospital  
• Fellowship: St Vincent Catholic Medical Center of NY - Staten Island Track  

Clinical Interests: Clinical Cardiology, Echocardiography, Cardiac Catheterization  

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Javed Suleman, MD  
Associate Clinical Professor of Medicine (Cardiology)  

Education and Training  
• MBBS: Sindh Medical College, Pakistan  
• Residency, Internal Medicine: Salem Hospital  
• Fellowship, Cardiology: Saint Vincent Hospital, Worcester, MA  
• Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY  

Clinical Interests: Clinical Cardiology, Coronary Intervention, Primary PCI  

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Dimitrios Bliagos, MD
Assistant Professor of Medicine (Cardiology)

Education and Training
• MD: SUNY Stony Brook
• Internship/Residency: NY Presbyterian Columbia University Medical Center
• Fellowship, General Cardiology: Montefiore Medical Center
• Fellowship, Interventional Cardiology: NY Presbyterian Columbia University Medical Center
• Fellowship, Endovascular Intervention: NY Presbyterian Columbia University Medical Center

Clinical Interests: Clinical Cardiology, Coronary Intervention, Endovascular Intervention, TAVR

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Adjunct Instructor Medicine (Cardiology)

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• MD: Facultad de Medicina-Universidad de la Republica
• Residency, Internal Medicine: Universidad de la Republica
• Residency, Internal Medicine: The Brooklyn Hospital Center
• Fellowship, Cardiology: The Brooklyn Hospital Center

Clinical Interests: Clinical Cardiology, Cardiac Catheterization, Interventional Cardiology

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Karthik Gujja, MD
Assistant Director, Endovascular Interventions
Clinical Instructor Medicine (Cardiology)

Education and Training
• Internship, Internal Medicine: Long Island College Hospital
• Fellowship, Cardiology: Beth Israel Medical Center
• Fellowship, Interventional Cardiology: Beth Israel Medical Center
• Fellowship, Endovascular Intervention/Peripheral: The Mount Sinai Hospital, NY

Clinical Interests: Peripheral Artery Disease, Endovascular Intervention, Venous Interventions

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Asim Hameedi, MD
Clinical Instructor of Medicine (Cardiology)

Education and Training
• MD: SUNY Downstate Medical Center, NY
• Residency: Albert Einstein College of Medicine/Montefiore Medical Center, NY
• Fellowship, Cardiology: SUNY Downstate Medical Center, NY
• Fellowship, Interventional Cardiology: SUNY Downstate Medical Center, NY

Clinical Interests: Clinical Cardiology, Interventional Cardiology

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Choudhury M. Hasan, MD
Assistant Clinical Professor of Medicine (Cardiology)

Education and Training
• MBBS: Dhaka Medical College, Dhaka, Bangladesh
• Residency, Internal Medicine: Brooklyn Hospital Center
• Fellowship, Cardiology: Brooklyn Hospital Center
• Fellowship, Interventional Cardiology: Deborah Heart and Lung Center

Clinical Interests: Cardiac Catheterization, Coronary Interventions, Echocardiography

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Timothy G. Jayasundera, MD
Clinical Instructor of Medicine (Cardiology)

Education and Training
• MD: Ross University School of Medicine
• Residency: Georgetown University Medical Center
• Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY
• Fellowship, Cardiology: Drexel Hahnemann University Hospital; Philadelphia, PA

Clinical Interests: Interventional Cardiology, Aspirin and Clopidogrel Resistance, Acute Coronary Syndromes

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Assistant Clinical Professor of Medicine (Cardiology)  

**Education and Training**  
- MBBS: Rangaraya Medical College, Kakinada, India  
- Residency: Lenox Hill Hospital, NY  
- Fellowship, Cardiology: Lenox Hill Hospital, NY  
- Fellowship, Interventional Cardiology: Lenox Hill Hospital, NY  

**Clinical Interests:** Clinical Cardiology, Cardiac Catheterization, Coronary Interventions  

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---

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- Residency, Internal Medicine: The Mount Sinai Hospital, NY  
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- Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY  

**Clinical Interests:** Clinical Cardiology, Noninvasive Cardiology, Coronary Interventions  

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Clinical Professor of Medicine (Cardiology)  

**Education and Training**  
- MD: Catholic University of Chile, Santiago  
- Residency, Internal Medicine: The Mount Sinai Hospital, NY  
- Fellowship, Cardiology: The Mount Sinai Hospital, NY  

**Clinical Interests:** Clinical Cardiology, Fellows Education, Cardiac Catheterization  

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Niranjan K. Mittal, MD
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Education and Training
• MBBS: Government Medical College, Patiala, India
• Residency, Internal Medicine: Jamaica Hospital, NY
• Fellowship, Cardiology: Brooklyn Hospital Center
• Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Clinical Interests: Clinical Cardiology, Cardiac Imaging, Interventional Cardiology
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Tien Nguyen, MD
Assistant Clinical Professor of Medicine (Cardiology)

Education and Training
• MD: New York Medical College
• Residency: Saint Vincent’s Medical Center, NY
• Fellowship, Cardiology: Saint Vincent’s Medical Center, NY
• Fellowship, Interventional Cardiology: Saint Vincent’s Medical Center, NY

Clinical Interests: Clinical Cardiology, Cardiac Catheterization, Coronary Interventions
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Clinical Instructor of Medicine (Cardiology)

Education and Training
• MD: Howard University College of Medicine
• Residency, Internal Medicine: Montefiore Medical Center/Albert Einstein College of Medicine
• Fellowship, Cardiology: The Mount Sinai Hospital, NY
• Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Clinical Interests: Cardiac Catheterization, Coronary Angioplasty, Peripheral Arterial and Venous Disease
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Jennifer Del Campo, MSN FNP-C, CCRN, CMC
Clinical Nurse Manager
Education and Training
• BSN: Nursing: Phil. College of Health Sciences
• MSN: Lienhard School of Nursing, Pace University
• Doctor of Medicine: MCU-FDTMF, Manila, Philippines
Jennifer Del Campo came aboard The Mount Sinai Hospital Cardiac Catheterization Laboratory in July 2005. Being a Pediatric Cardiologist as a background made her an excellent teacher. She is a certified critical care nurse, adult nurse practitioner, and is a member of the Sigma Theta Tau Nursing Honor Society. Jennifer became the lead NP for two years and in 2016, accepted the managerial position. She effectively manages a unit with a diverse staff of more than 167 health professionals.

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Gregory Gojkovich
Operations Manager
Education and Training
• AA Degree, Moorpark College, California
Greg Gojkovich joined The Mount Sinai Hospital Cardiac Catheterization Laboratory in January 1987. In 1992, he accepted a cardiac catheterization laboratory operational manager position at Beth Israel Medical Center, New York, NY. He returned to Mount Sinai in 2001.

Phone: 212-241-1548   Email: gregory.gojkovich@mssm.edu
Nurse Practitioner Team

The Mount Sinai Hospital’s dedicated staff of nurse practitioners work closely with the physicians in planning and implementing care from the time of intake to discharge, ensuring a quality experience at all points in the patient’s visit.

Interventional Cardiology Fellows

Mount Sinai Heart’s Interventional Cardiology Fellowship Program is the largest in the country, educating the next generation of clinical cardiology and interventional cardiology specialists. This well-regarded program, which combines academic and hands-on experience, has graduated physicians who are serving as noted leaders in community and academic medical centers.
Interventional Database Team
Srushti Shah, Elena Ramos, Roja Thapi, Birju Narechania, Poojay Vitay

Interventional Research Team
Hiroshi Ueda, Hugo Bloise-Adames, Safwan Kezbor, Miguel Vasquez, Nanik Ram, Pedro Veras, Michael Gallo, Julie Singh, Yuliya Vengrenyuk, Mita Tewar, Takahiro Yoshimura

Supporting Staff
Michelle Brewster, Debra Bradley, Radha Gokul, Shulandia Avila, Juanita Gamboa, Maria Directo, Carol Henry, Daysy Carate, Kimberley Kostiw, Era Zuberko
CCC Live Cases features seminars highlighting in-depth procedural techniques for managing complex cardiac cases, streamed in real time online. Viewers are encouraged to participate in our online didactic discussion.

**Learning Objectives:**
- Discuss the rationale for choice of intervention for complex cases
- Demonstrate the use of plaque modification techniques
- Demonstrate the application of large, randomized clinical trial results within an interventional clinical perspective

**Target Audience:**
Cardiologists, interventional cardiologists, fellows, cardiovascular technicians, and cardiac catheterization laboratory nurses.

### Complex Coronary Cases
- Third Tuesday of each month
- 8:00 AM
- January 17, 2017
- February 21, 2017
- March 21, 2017
- April 18, 2017
- May 16, 2017
- June 20, 2017
- July 18, 2017
- August 15, 2017
- September 19, 2017
- October 17, 2017
- November 21, 2017
- December 19, 2017

### Peripheral Interventions
- Fourth Wednesday of each month
- 8:00 AM
- January 25, 2017
- February 22, 2017
- March 22, 2017
- April 26, 2017
- May 24, 2017
- June 28, 2017
- July 26, 2017
- August 23, 2017
- September 27, 2017
- October 25, 2017
- November 22, 2017
- December 27, 2017

### Structural Heart Live Cases
- Second Tuesday of every other month, 9:00 AM
- January 10, 2017
- March 14, 2017
- May 9, 2017
- July 11, 2017
- September 12, 2017
- November 14, 2017
- December 27, 2017

*AVERAGE 6,000 PAGE VIEWS PER MONTH IN 127 COUNTRIES.*

www.ccclivecases.org  www.peripheralinterventions.org  www.structuralhearthlivecases.org
Monday, June 12th
Endovascular Fellows Course

Tuesday, June 13th &
Wednesday, June 14th
LINC Mount Sinai
Endovascular Symposium

Thursday, June 15th
Coronary / Structural Heart Symposium

Friday, June 16th
Interventional Cardiology Board Review
Nurse / Technologist Symposium

CORONARY / STRUCTURAL HEART
SYMPOSIUM DIRECTORS
Samin K. Sharma, MD, FACC, FSCAI
Annapoorna S. Kini, MD, MRCP, FACC
Roxana Mehran, MD, FACC, FSCAI

CO-DIRECTORS
George Dangas, MD, PhD, FACC, FSCAI
Jason Kovacic, MD, PhD, FACC, FSCAI
Joseph M. Sweeney, MD, FACC
Pedro R. Moreno, MD, FACC
Nitin Barman, MD, FACC

ENDOVASCULAR
SYMPOSIUM DIRECTORS
Prakash Krishnan, MD, FACC
Dierk Scheinert, MD

CO-DIRECTORS
J. Michael Bacharach, MD, MPH, FACC, FSCAI
James F. McKinsey, MD, FACS
Andrej Schmidt, MD
Giovanni Torsello, MD, PhD

NURSE / TECHNOLOGIST
SYMPOSIUM DIRECTORS
Beth Oliver, DNP, RN
Antonietta Tolentino, MSN, ANP-C

JUNE 13-16, 2017
New York, New York

Sponsored by The Zena and
Michael A. Wiener Cardiovascular Institute
and the Marie-Josée and Henry R. Kravis Center
for Cardiovascular Health of
The Icahn School of Medicine at Mount Sinai

www.cccsymposium.org
#1: New York Magazine
Dr. George Dangas (3rd year in a row), Dr. Roxana Mehran (3rd year in a row), and Dr. Pedro Moreno listed as Best Doctors.

#2: New York Times Magazine
Dr. Samin K. Sharma (8th year in a row), Dr. Annapoorna S. Kini (5th year in a row), and William Schwartz, MD were listed as Super Doctors in 2016.

#3. Castle Connolly Top Doctors
Dr. Samin K Sharma, Dr. Annapoorna Kini, Dr. Prakash Krishnan, Dr. George Dangas, Dr. Pedro Moreno, Dr. Roxan Mehran, Dr. Joseph Sweeney, and Dr. William Schwartz

#4: Dr. Samin Sharma and Dr. Annapoorna Kini received Endowed Professorships

#5. Dr. Vishal Kapur appointed Director of Endovascular Services at Mount Sinai St. Luke’s
# Mount Sinai Heart Directory

<table>
<thead>
<tr>
<th>Area</th>
<th>Telephone</th>
</tr>
</thead>
<tbody>
<tr>
<td>MS Heart Director</td>
<td>212-241-7911</td>
</tr>
<tr>
<td>Cardiac Nursing</td>
<td>212-241-3483</td>
</tr>
<tr>
<td>Cardiac Rehab Program</td>
<td>212-241-8597</td>
</tr>
<tr>
<td>Cardiology Administration</td>
<td>212-241-4030</td>
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<tr>
<td>Cardiology Appointments</td>
<td>212-241-1540</td>
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<tr>
<td>Cardiology Privileges</td>
<td>212-241-4029</td>
</tr>
<tr>
<td>Cardiothoracic Surgery</td>
<td>212-659-6800</td>
</tr>
<tr>
<td>Cardiovascular MRI and CT Imaging</td>
<td>855-MSHEART</td>
</tr>
<tr>
<td>Catheterization Laboratories</td>
<td>212-241-5881</td>
</tr>
<tr>
<td><strong>Cardiac Catheterization Laboratory Assistance (‘any issues’)</strong></td>
<td><strong>212-241-0935</strong></td>
</tr>
<tr>
<td>Catheterization Laboratory Events</td>
<td>212-241-0592</td>
</tr>
<tr>
<td>Catheterization Laboratory Office</td>
<td>212-241-4021</td>
</tr>
<tr>
<td>Catheterization Laboratory Research</td>
<td>212-241-0229</td>
</tr>
<tr>
<td>Catheterization Laboratory Scheduling</td>
<td>212-241-5136</td>
</tr>
<tr>
<td>Coronary Care Unit</td>
<td>212-241-7222</td>
</tr>
<tr>
<td>Electrophysiology/Pacemakers</td>
<td>212-241-7272</td>
</tr>
<tr>
<td>Genetic Disorders</td>
<td>212-241-3303</td>
</tr>
<tr>
<td>Heart Failure/Transplantation</td>
<td>212-241-7300</td>
</tr>
<tr>
<td>Lipid Management</td>
<td>212-241-7651</td>
</tr>
<tr>
<td>MS Heart Information Technology</td>
<td>212-241-4026</td>
</tr>
<tr>
<td>Noninvasive Cardiology</td>
<td>855-MSHEART</td>
</tr>
<tr>
<td>Pediatric Cardiology</td>
<td>212-241-8662</td>
</tr>
<tr>
<td>Pulmonary Hypertension</td>
<td>212-241-7300</td>
</tr>
<tr>
<td>To Transfer a Patient</td>
<td>212-241-6467</td>
</tr>
<tr>
<td>Vascular Laboratory</td>
<td>212-241-6773</td>
</tr>
<tr>
<td>Vascular Surgery</td>
<td>212-241-5315</td>
</tr>
</tbody>
</table>

Publication of this 2016 *Clinical Outcomes & Innovations* Report was made possible through the following generous gifts:

- In honor of Theresa from her loving daughter
- Marvin and Donna Schwartz

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www.onwardpublishing.com
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Marketing and Communications
The mission of the Cardiac Catheterization Laboratory at Mount Sinai Heart is:

“To improve outcomes and safety of interventional patients by delivering clinical innovations, unrivaled research, and personalized clinical care as a Team Concept.”