Dear Colleague:

We from the Cardiac Catheterization Laboratory at Mount Sinai Heart take great pride in presenting our patient-centered 2011 outcomes report, a comprehensive overview of the work being done here at the nation’s largest and finest cardiac catheterization laboratory to treat a variety of cardiac conditions. Public reporting of quality and patient safety data is increasingly mandated for transparency by various organizations and stakeholders and we offer our data in comparison to various regional and national standards. Technical achievements in percutaneous intervention have resulted in a relentless drive for procedural excellence; our outcome data over the last five years supports our claim that we at Mount Sinai have perfected the art of PCI.

The management of CAD patients is rapidly changing today, with medical therapy playing a major role in the management of mild to moderate CAD patients and PCI in moderate to severe CAD, while coronary artery bypass surgery has been shown to improve long-term survival of patients with extensive CAD. Nevertheless many of the stable patients with extensive CAD undergo PCI for symptom relief and quality of life improvement. Stable interventional growth with declining complications despite increasing complexity of cases has been made possible by teamwork and dedication for treating each patient as an individual. We are also committed to the universal use of innovative, evidence-based standardized medical protocols; this has contributed to our extraordinary success. It is not unusual for patients who have been deemed “inoperable for advanced care” to come to us, be treated successfully, and go home with a smile on their face.

In order to remain at the top, we will continue to employ the cutting-edge technology and techniques that are the hallmarks of our success. In this issue we provide the details of innovations that have contributed to our national and international recognition through stories of grateful patients. Our goal for 2012 is to rise to eminence from excellence in the field of interventional cardiology.
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Dear Colleagues:

It is our honor to share with you the fourth edition of the Cardiac Cath Lab Clinical Outcomes Report. This report provides a look into the high caliber of care and medical research that takes place at The Mount Sinai Hospital.

The 2011 New York State Department of Health report, *Percutaneous Coronary Interventions (PCI) in New York State* (2006-2008), recognized our Interventional Cardiology Cath Lab for the lowest complication and mortality rates for PCI among New York State’s 54 cardiac catheterization labs. The Cath Lab achieved these results while performing the highest number of PCI procedures in the State.

Carefully tested and practiced protocols enable the lab’s physicians and interventionalists to treat the most complex cases of cardiovascular disease with virtually no complications, and guide the delivery of care from the moment a patient enters the medical center until they return home.

The Cath Lab’s team of interventionalists, nurses, technicians, and support staff, under the directorship of Dr. Sharma and Dr. Kini, is committed to continuous quality improvement. The team reviews its cases, incorporates data from those cases into its medical protocol, and communicates that protocol clearly and effectively to each member of the medical team. This teamwork and dedication to providing superior outcomes for our patients exemplify Mount Sinai’s commitment to providing excellent patient care.

We hope you find this edition of the Cardiac Cath Lab Clinical Outcomes Report informative, and we are pleased to have this opportunity to commend the Cath Lab once again.
A MESSAGE FROM VALENTIN FUSTER, MD, PhD, MACC

Cardiovascular medicine is an exciting field in which to practice today. Advances in diagnosis and treatment are continuous, and Mount Sinai Heart, established only six years ago, is proud to be recognized as a world leader.

The Cardiac Catheterization Laboratory, with Samin K. Sharma, MD, as its distinguished director, has played an important role in Mount Sinai Heart’s rise to national prominence. Dr. Sharma’s high clinical standards and his gift for leadership have helped him put together a team of interventionalists and support staff that is unsurpassed.

The Cath Lab is the busiest facility of its kind in New York State. The men and women on staff are providing care to patients, many of whom are critically ill and require complex life-saving procedures, day and night. There is never any compromise of quality, however; every patient receives the same high level of care and is treated with the same respect and concern.

You will see as you peruse this latest edition of the Clinical Outcomes Report for the Cardiac Cath Lab that in 2012 we have continued to maintain or even exceed our extremely high standards of care. You will also see that we have continued to explore many intriguing new avenues of diagnosis and treatment that will help us maintain our position on the forefront of developments in 2013 and beyond.

As an indication of its prestige, our institution is often invited to participate in important clinical studies in the field of intervention that hold out new hope for certain patient populations. One such study is the CoreValve U.S. Pivotal Trial. The device was designed to replace a diseased aortic heart valve percutaneously via catheter, and the first procedure was performed by Dr. Sharma and Dr. David H. Adams, MD, Chairman of cardiothoracic Surgery, right here at Mount Sinai, in December 2010.

Our custom has been to include patient “success stories” on the pages of this report, and this year you will see that four patients featured were enrolled in the clinical trial and received CoreValves delivered percutaneously. All these grateful patients were deemed too high risk for open heart surgery, and all have made a good recovery.

And that is at the heart of what we do: Whether the treatment we offer is experimental or tried and true, simple or highly complex, it is our mission to extend and enhance the quality of the lives of the thousands of people who entrust their care to us.
THE CARDIAC CATHETERIZATION LAB

An Overview of Services and Outcomes

It is said, “Individuals play the game but teams win championships.” The concept of teamwork is our guiding principle in the Cath Lab and is the main reason for our success.

Mount Sinai Heart, encompassing clinicians, scientists, nurses, and associated caregivers under the leadership of visionary director Valentin Fuster, MD, PhD, has emerged as a premier center delivering a complete range of clinical and research options to patients suffering from a variety of cardiovascular ailments. The extraordinary care we offer has resulted in our ascent nationally from 50th in 2007 to 11th in 2011 (US News & World Report 2011).

The Cardiac Catheterization Laboratory at Mount Sinai Heart is the busiest interventional catheterization laboratory in the United States. Our Cardiac Cath Lab, consisting of six adult cath rooms (three equipped for endovascular procedures), has established a tertiary center for complex coronary, valvular, and vascular interventions. Two of the cath rooms (hybrid cath lab) are equipped to perform transcatheter aortic valve replacement (TAVR). All cath rooms are equipped with intravascular ultrasound (IVUS) and four rooms have fractional flow reserve (FFR) capability. We incorporate technological advances, such as optical coherence tomography (OCT) and near-infrared spectroscopy (NIRS), as soon as they become clinically available.

To efficiently manage the growing cath volume and the complexity of invasive cases, our physical infrastructure and our Cath Lab staff remain under constant stress. The numbers of both medical and nonmedical cath lab staff have shown tremendous growth, to over 165, with the ultimate goal of delivering safe, appropriate, and excellent care.
Presently there are five full-time senior attendings, 10 full-time affiliate attendings, nine voluntary interventional attendings, four voluntary cath attendings, three CHF/transplant attendings, one pediatric cath attending, eight interventional fellows, and 15 Cath Lab nurse practitioners. Each member of the Cath Lab staff has a strong work ethic and takes pride in his or her contribution to the principal goal of the lab: delivery of efficient and safe care to patients in need. As a result, the Cath Lab 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 40 percent of our 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; the majority are discharged home next day. The following chart depicts our inpatient volume, average length of stay (ALOS, which is usually 0.85 of expected LOS), and case mix index (CMI, measure of a patient’s medical acuity based on associated medical conditions).

In this competitive environment, only the best can flourish, and that is exactly what our Cath Lab has done, delivering the best and the safest invasive/interventional care to cardiac patients, with innovation and procedural excellence. On the following pages are some of the important attributes of the Cardiac Cath Lab.
The volume of diagnostic cath and interventional procedures at the Mount Sinai Cardiac Catheterization Laboratory has experienced substantial growth over the last five years, with significant increase in endovascular and valvular interventions. 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 valve), transcatheter aortic valve replacement/implantation (TAVR/TAVI) for stenosed aortic valves, alcohol septal ablation (for hypertrophic obstructive cardiomyopathy (HOCM)), and interventions for other structural heart diseases, such as closing of ASD, PFO, or paravalvular leak. Procedures in this last category, performed by our pediatric cardiologist, Barry Love, MD, are not counted in our interventional numbers. In 2011 we performed 5,663 interventions: 4,707 PCI, 776 endovascular interventions, 125 balloon aortic valvuloplasties, 18 balloon mitral valvuloplasties, 26 TAVR, and 11 alcohol septal ablations. Carotid stenting is now routinely being performed by our interventionalists, in conjunction with vascular surgeons; 25 cases were successfully performed in 2011. The majority of PCIs (95 percent) are done using stents (DES in 91 percent; BMS in 9 percent) with adjunct 10 percent rotational atherectomy and 2 percent thrombectomy/distal protection device and the remaining 5 percent PTCA only. Some of the growth can be attributed to our various outreach activities, allowing community physicians, an integral part of the Mount Sinai referral network, to offer tertiary care to
their patients in the local catchment area. As in previous years, affiliate and voluntary attendings contributed about 24 percent of cath/PCI volume in 2011, with a low rate of complications as with full-time attendings. Thanks to our established reputation for handling complex coronary and valvular cases with great success and safety, about one third of our interventional patients are referred by physicians (internists, cardiologists, and interventionalists) outside our hospital network.

NYS DOH-Reported PCI Volumes in Comparison to Other NY Centers

Mount Sinai Hospital’s Cardiac Catheterization Laboratory has shown tremendous growth in all types of interventions over the past five years, as the chart at right shows. Our lab rose to the top position among New York State hospitals in 2005 and has held a commanding lead of about 2,000 interventions over any other center since 2006, according to NY State Department of Health statistics.

Interventional Outcomes and Temporal Trends in Complications

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. We continue to improve our outcomes every year, with unprecedented extremely low procedural complications in 2011; first-time combined major complication of death, large MI, urgent CABG, and CVA cases under 0.5 percent.
This remarkable growth with low complications has been achieved despite high complexity and co-morbid medical conditions of patients being treated in the Cath Lab. Reports of risk-adjusted PCI mortality over the last 15 years by the NYS Department of Health have consistently placed the Mount Sinai Heart Cath Lab among the lowest for in-hospital and 30-day risk-adjusted mortality. The recent New York State DOH report of 30-day risk-adjusted mortality for year 2008 has shown our incidence of 0.63 percent for all cases, 0.45 percent for elective cases, and 1.78 percent for emergency PCI cases; the lowest in the state and about 30 percent lower than the statewide average. We are the only center to receive a double-star (**) notation of superior safety in all three PCI categories (all cases, elective, and emergent). Receiving the double star
in all three PCI categories is unprecedented in history and for the NYS DOH PCI Department since its inception in 1994.

This lower 30-day risk-adjusted mortality can be attributed in large part to the experience and high volume of the five senior full-time interventionalists, who perform over 4,000 cases per year. As in earlier reports, in the 2008 report, Dr. Sharma was awarded the double star by NY State denoting significantly lower 30-day risk-adjusted mortality among approximately 600 interventionalists practicing in the state. These low complication rates, credited to a uniform protocol across all staff, are all the more remarkable for the fact that our Cath Lab accepts the most difficult coronary and valvular cases, many of them deemed too risky or “not-doable” elsewhere. The comparative data of patients’ clinical characteristics, as shown in the table on page 11, confirm significantly higher adverse features of PCI patients treated at MSH compared to New York State, yet significantly better outcomes in most of the commonly reported procedural complications.

Comparison of Mount Sinai Hospital Interventional Outcomes with Others

The graph at right shows the superior interventional outcomes of PCI patients at Mount Sinai Hospital in comparison to NY State, ACC-NCDR, and Cleveland Clinic Hospital.
Complex Coronary Interventions, SYNTAX Score and Transcatheter Aortic Valve Replacement

The SYNTAX (Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery) trial, conducted at 85 sites in 17 countries, sought to establish a grading tool for determining the complexity of coronary artery disease and helping interventionalists, surgeons, and patients decide between angioplasty (PCI) and open-heart surgery. This measurement, known as a SYNTAX score, is an important tool in our Cath Lab.

Since January 2010, we at Mount Sinai Heart have been incorporating SYNTAX scores in stratifying patients with advanced CAD for choice of revascularization modality (PCI vs. CABG). Based on the original SYNTAX study, patients who were not at high risk for undergoing bypass surgery and whose scores were 33 and higher were preferentially referred for CABG.
“Dr. Sharma is incredibly busy, but when I go in for follow-up appointments he always has time to chat.”

Patient: Margaret Callahan, 82-year-old woman
Diagnosis: Acute on chronic diastolic heart failure, aortic stenosis
Treatment: Transcatheter aortic valve implantation using 26 mm CoreValve

Like many people of her generation, Margaret Callahan started smoking at a young age. "My diet was coffee and cigarettes," she said. "We didn't know back then that it was so bad for our health." In November of 1977 she suffered a heart attack. She stopped smoking and began to eat healthy foods, but "the damage was done," she said. Not long afterward she was diagnosed with emphysema and chronic obstructive pulmonary disease (COPD).

Her breathing difficulty increased, and in 2010, her cardiologist sent her to Columbia, where they were enrolling patients in a clinical study of an implantable aortic valve. She underwent some preliminary testing and then was told that they were postponing the trial. She called her cardiologist, who said, "You can't wait." He made a call to Dr. Sharma.

"Dr. Sharma told me to come in the next day," she said, "and before I knew it I was enrolled in the CoreValve trial. I was not a candidate for open-heart surgery, so I would be in the minimally invasive arm of the trial. My procedure was performed on January 21, 2011, a day later than originally scheduled because they had to construct a special sheath to protect my abdominal aneurysm from the catheter. It was a piece of cake. My recovery was smooth, and I'm feeling much better.

"Dr. Sharma is incredibly busy, but when I go in for follow-up appointments he always has time to chat. I'm so grateful to Mount Sinai and Dr. Sharma for the wonderful care I received."

Recent SYNTAX trial follow-up data presented in November 2011 at TCT (Transcatheter Cardiovascular Therapies), however, revealed that patients in the CABG arm, including those whose SYNTAX scores were in the intermediate range (23 to 32), were found at four years out to have significantly lower endpoint of death, myocardial infarction, or revascularization when compared to patients undergoing PCI with implantation of drug-eluting stents. This observation held true for both diabetic and nondiabetic patients. (Outcomes for patients with low SYNTAX scores, below 23, were similar for both groups.)
We conclude from this data that patients with three-vessel CAD and SYNTAX scores that fall in the intermediate or high range (23 to 32 or >32) should categorically be advised to undergo CABG, unless the following situations or comorbidities are present:

- Acute MI (STEMI or non-STEMI)
- Class IV angina with a well-defined culprit lesion for PCI
- Age above 80
- Prior CVA or recent TIA
- Severe COPD (FEV1 below 50 percent predicted) and on chronic bronchodilator therapy
- Body mass index above 50
- LV ejection fraction below 30 percent
- Participation in IRB-approved PCI trial

It is important to note that when confronted with the choice between bypass surgery and PCI, the natural human tendency is to select the latter, sometimes despite the physician’s recommendation. In fact, 50 percent of patients, despite recommendations to the contrary, elect to undergo PCI. It is easy to understand patients’ reluctance. Many of these patients with advanced CAD are referred for high-risk intervention, which is routinely done with no or minimal complications. Open-heart surgery is the very definition of an invasive procedure, involving administering general anesthesia, cutting open the chest, and placing the grafts in the heart. The patient who undergoes open-heart surgery spends a week or more in the ICU and a hospital bed. The patient who undergoes PCI is awake and aware and may even go home the same day (40 percent at MSH).

To overcome this predisposition to select PCI, it is essential that the patient with three-vessel CAD and an intermediate to high SYNTAX score should not be asked to select PCI or CABG while lying on the cath table, but instead should be taken out of the Cath Lab and brought into another area (e.g., the holding area or the telemetry unit). Here, the discussion can be conducted calmly and

![Patients with SYNTAX Score ≥33](image)
unemotionally, and all data can be presented to the patient, most importantly the long-term outlook. Patients still opting for PCI are now required to consult with a cardiac surgeon. The patient’s firm refusal is accepted only after the conversation described above has been conducted. (The only exception to this rule is the case where the referring MD, who is not the interventionalist, is physically present and strongly objects to CABG based on his or her own beliefs or the wishes of the patient that have been expressed to him.)

At Mount Sinai Heart, educating patients and guiding them in making informed decisions is one aspect of the superior care we offer. To stay at the forefront of advances in thinking about PCI versus CABG for patients with complex coronary artery disease, we are collecting

“T’m breathing easy and enjoying life after TAVI. Dr. Sharma and his team brought me back. I’m very grateful.”

Patient: Jay Stafford, 78-year-old man
Diagnosis: Acute on chronic diastolic heart failure, aortic valve disease
Treatment: Transcatheter aortic valve implantation using 29 mm CoreValve

“I’m breathing easy and enjoying life after TAVI. Dr. Sharma and his team brought me back. I’m very grateful.”
the data in 2012 on our amended protocol by analyzing the triage of all three-vessel CAD patients with SYNTAX scores of 23 and above. Our data of 2011 have shown that patients with high SYNTAX scores are increasingly undergoing CABG rather than PCI.

Transcatheter Aortic Valve Replacement) Implantation (TAVR/TAVI)

In aortic stenosis (AS), the aortic valve narrows, limiting blood flow from the aorta to the rest of the body. It affects an estimated 300,000 people worldwide and is associated with considerable morbidity and mortality. The prevalence is increasing as the population ages, afflicting 2 to 3 percent of North Americans over age 65. Approximately one third of these patients are considered too high risk for open-heart surgery, which until recently was the only available treatment option. Approximately 45,000 surgical aortic valve replacements are done in the U.S.— and it is estimated that approximately another 100,000 patients with severe AS will be suitable for less invasive percutaneous aortic valve replacement.

The development of percutaneous aortic valve replacement has opened a new era in treatment for aortic stenosis, and interventional cardiologists and cardiothoracic surgeons at Mount Sinai Heart are at the forefront of the investigation of transcatheter aortic valve replacement or implantation (TAVR or TAVI).

TAVR involves deployment of a prosthetic valve via a transfemoral catheter, or less commonly, a subclavian arterial or transaortic approach. Occasionally the procedure involves a transapical left ventricular approach. Unlike open surgical aortic valve replacement, which involves removing the existing valve and replacing it with a mechanical or biological substitute, in TAVR an implantable bioprosthetic valve is mounted inside a collapsible metallic frame. In its collapsed state, the valve and
“Because her heart failure had slowly worsened over so many years, Mom didn’t realize how bad she was feeling until the procedure was finished”

Patient: Santina Persichilli  
91-year-old woman

Diagnosis: Extensive left main and 3v CAD and aortic valve disease

Treatment: Transcatheter aortic valve implantation using 26 mm CoreValve and PCI of left main, CAD and Lex

Mrs. Persichilli suffered for many years from high blood pressure and congestive heart failure. She retired to Florida, but when she was 87 her health had deteriorated to the point where her daughters moved her back up north to oversee her care.

Her cardiologist on Long Island brought up the possibility of coronary artery bypass graft (CABG) surgery, but he and her daughters felt that the risk of undergoing open heart surgery under heavy anesthesia was too great.

“Her doctor knew Dr. Sharma, and he knew about the CoreValve clinical trial, and he suggested that my mother might qualify to be enrolled,” said Fran Troutman, a daughter. “So we came to Mount Sinai. She passed all the tests, and had arteries opened by rota-device and stenting, and her valve procedure was scheduled for November 15, 2011.”

Mrs. Persichilli’s surgery went smoothly. “Dr. Sharma came out to the family waiting area to tell us that the procedure was finished, and he was smiling from ear to ear,” Mrs. Troutman recalled. “We could tell that he was pleased with the outcome. And her recovery went just as well.

“Because her heart failure had slowly worsened over so many years, she didn’t realize how bad she was feeling until the procedure was finished and she was suddenly so much better,” said Mrs. Troutman. “She says she should have done it a long time ago. Of course, I have to remind her that it wasn’t available until very recently. We are so grateful that the CoreValve was developed for patients like my mother, and that we found Mount Sinai and Dr. Sharma.”

the supporting frame have a diameter of just 6–8 mm, which facilitates catheter-based delivery. An experienced interventionalist expertly positions the framed valve within the orifice of the diseased valve and expands the device. As the frame dilates the opening, the new valve inside opens and begins functioning immediately. In contrast to conventional surgery, TAVR can be performed under light general anesthesia and without cardiopulmonary bypass, making recovery faster and easier. For the thousands of patients who are too frail or ill to undergo open-heart surgery, TAVR is offering new hope.
In the pivotal PARTNER (Placement of Aortic Transcatheter Valves) Trial, Cohort B was composed of 358 patients with severe, symptomatic AS deemed surgically inoperable for traditional open-heart surgery due to high-risk clinical features. TAVR performed using the Edwards SAPIEN™ valve was associated with a 20 percent absolute reduction in all-cause mortality during the first year, from 50 percent in the medically treated control arm to 30 percent in the group undergoing TAVR. The composite endpoint of death or repeated hospitalization was reduced by 30 percent. The U.S. Food and Drug Administration (FDA) has approved the Edwards SAPIEN valve for use outside the context of a clinical trial. Recently presented two-year data continued to show superiority of TAVR over standard therapy.

In the pivotal PARTNER Trial Cohort A, of high-risk aortic stenosis particularly one year outcome of death were similar between TAVR vs. SVAR with higher stroke rate in the TAVR group (>2x).

Mount Sinai is a principal site for evaluation of the Medtronic CoreValve®, and in fact the first CoreValve transcatheter aortic valve implantation procedure was performed here, on December 17, 2010, by Samin K. Sharma, MD, and David H. Adams, MD. The patient was an 88-year-old man with recurrent heart failure brought on by severe aortic stenosis. He had undergone balloon aortic valvuloplasties three months earlier, but his symptoms recurred. His aorta was highly calcified, and to prolong his life, CoreValve implantation was deemed the only option.

The Medtronic CoreValve, although in some ways comparable to the Edwards SAPIEN valve, is thinner and is deployed through a smaller sheath (18 vs. 24 French). Given this obvious advantage, physicians at Mount Sinai Heart have been eager to implant the device and have taken a leadership role in its adoption. The CoreValve is available only to patients enrolled in the CoreValve U.S. Pivotal Trial.
“I put my life in Dr. Sharma’s hands without any reservations, and I’m so glad I did.”

**Patient:** Mildred Faist, 85-year-old woman

**Diagnosis:** Acute on chronic systolic heart failure, aortic valve disease

**Treatment:** Transcatheter aortic valve implantation using 29 mm CoreValve

Mrs. Faist has long suffered from pulmonary hypertension. In 2011, she made an appointment to see her cardiologist because she was having trouble breathing, and that doctor sent her immediately to her local hospital. She was given an angiogram, and the doctor who performed it told her she was in heart failure. “Yours is the most complicated case I’ve ever seen. I’m sending you to Mount Sinai.”

“At Mount Sinai they put me through all kinds of tests,” she said, “and then they told me I qualified to be enrolled in the clinical trial for the CoreValve. My condition was so serious that I wasn’t a candidate for open-heart surgery, so I was glad to learn that the procedure would be minimally invasive.”

It was performed on June 7, 2011. “I was apprehensive, naturally,” Mrs. Faist said, “but everything went fine. My recovery was surprisingly quick. In fact, I think that even Dr. Sharma was surprised at how soon I was back to my old routines, driving my car, doing my shopping. I felt better than I had felt in years.

“From the moment I first met him, I knew that Dr. Sharma was a warm, caring person as well as a skilled physician. I put my life in his hands without any reservations, and I’m so glad I did.”

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CoreValve U.S. Pivitol Trial
Enrollment Flowcharts — TAVR vs. SAVR
Mount Sinai investigators are engaged in developing methods to treat other valve diseases using minimally invasive, catheter-based techniques. Therapies for percutaneous reduction of mitral regurgitation (MR) have shown promise in early clinical trials, for the treatment of another commonly encountered valve disorder called mitral regurgitation. When mitral regurgitation is present, blood flows backwards through the mitral valve when the heart contracts. This reduces the amount of blood that is pumped out to the body. Evalve uses a clip to limit the mitral leaflet movement. Results in the EVEREST Trial of Mitral Clip vs. Surgical MVR have been encouraging.

It seems likely that surgical valve repair will remain the optimum strategy for most patients with severe
MR. As we have seen with TAVR, however, novel procedures may become the preferred approach; they offer new hope for patients at high risk for open-heart surgery.

The introduction of catheter-based approaches to management of patients with structural heart disease such as severe AS (and selected cases of MR) is changing the way patients are managed throughout the technologically developed world. As this trend continues, patients will no longer be routinely referred to an interventional cardiologist or a cardiac surgeon based upon a specific cardiac diagnosis, but instead will be evaluated by both types of specialists, who will confer to select the optimum approach for each patient. The close working relationships between our cardiac surgeons and our interventional cardiologists, and the other key services we offer, put Mount Sinai Heart at the forefront of this revolution.

At Mount Sinai Heart, the collaboration of skilled surgeons and interventional cardiologists (the Heart Team concept), with access to advanced diagnostic imaging data and cutting-edge technologies like TAVR, ensures the best clinical outcomes based on application of the latest modalities to the individual patient. Coupled with the experience that comes from high interventional volumes for both vascular and valvular disorders, the collaborative approach continues a long tradition at Mount Sinai of offering the highest-quality cardiovascular care.
Left Ventricular Assist Devices and Chronic Total Occlusion

Left Ventricular Assist Devices in PCI

A left ventricular assist device (LVAD) is employed during percutaneous coronary intervention (PCI) in cases where there is decreased left ventricular function, particularly when the ejection fraction is 30 percent or less. Its use has been demonstrated to be of benefit for patients with concomitant mitral regurgitation.

In patients with complex coronary disease (left main, calcific, long lesions, total occlusion in two or three vessels), another layer of complexity is the possibility of instability — lowered blood pressure and change in heart rate — during PCI. If the LV device is not used in complex cases, when there is any sign of hypotension or tachycardia, the procedure may be cut short without obtaining complete vascularization. The cardiac support from the LVAD provides the interventionalist with the time to complete the procedure comfortably, especially if performing rotational atherectomy. Since these cases often take longer than usual, LV device support is essential if the interventionalist is to achieve complete revascularization as planned.

The LV device can be used on almost every high-risk PCI patient; exceptions are those with aortic valve disease, fresh left ventricular thrombus, and peripheral vascular disease. It has also been shown to be beneficial in cases of acute myocardial infarction with cardiogenic shock, when the LV device can be left in situ for more than 24 hours.
“After the first procedure my energy level was up, and I felt even better after the second.”

Patient: David Abramson, 71-year-old male
Diagnosis: Angina; coronary atherosclerosis of native vessel
Treatment: Successful intervention of left circumflex artery and insertion of drug-eluting stent

Mr. Abramson has always enjoyed working out, and he refused to be sidelined by health issues, even after he was diagnosed with essential hypertension and prescribed medication. Then he began to notice that he was short of breath, and his doctor ordered a sonogram. To his surprise, it showed that he had suffered a silent heart attack.

A stress test revealed slight damage to his heart, and he did three months of cardio rehab. Another cardiologist ordered another stress test and then sent him for an angiogram. “I tried to put it off,” he said, “but that night at 2:30 a.m. the doctor called me and said it had to be done right away. He gave me the name of a doctor at Mount Sinai who was tops in the field, and I reluctantly agreed to schedule the procedure.

“As I was wheeled into the operating room, I heard a beautiful voice say, ‘You’re not afraid because you know you are in good hands.’ That was Dr. Kini. And she was right. I was no longer afraid.”

Mr. Abramson underwent two separate procedures, two weeks apart. “Every person I encountered at Mount Sinai was so responsive, so knowledgeable,” he said. “After the first procedure my energy level was up, and I felt even better after the second. I’ve lost 20 pounds, and I’m walking farther, faster. I feel as if I’ve been given a gift — the greatest medical care, by the greatest people. I have a new lease on life.”

The new-generation LV assist device, the Impella® 2.5, manufactured by Abiomed, is designed for ease of use. The prep is user-friendly for cath lab nurses and techs, so the system can be used in emergency situations. The catheter can be advanced with or without a wire. For patients with tortuous calcified aortas who have had aortic or iliac artery stents implanted, the new device can be negotiated through the diseased iliac artery and aorta using a wire.
Chronic Total Occlusion

A chronic total occlusion (CTO), found in 15 to 20 percent of all patients undergoing coronary angiography, is a complex blockage of a coronary artery that has existed more than three months. Because of their length and composition, which includes calcium and other fibrous materials, CTOs pose a technical challenge for even the most experienced interventionalist. But the benefits of opening these complex blockages include relief of angina; elimination of ischemia in asymptomatic patients; and improved left ventricular (LV) function.

The guidelines of the American College of Cardiology recommend coronary artery bypass graft (CABG) in cases of CTO in more than two vessels. Patient selection is very important. Younger patients with normal left ventricular function in the presence of ischemia are usually referred for CABG. For elderly patients, however, with evidence of LV dysfunction and other comorbidities, CABG can be a high-risk, highly invasive operation with a long, difficult recovery. For these patients, we at Mount Sinai’s Cath Lab have been working to develop better methods of PCI.

The antegrade approach has been the traditional method of PCI intervention for those who meet the guidelines in a CTO. Our success rate for antegrade intervention is approximately 80 percent, slightly higher than other cath labs even staffed by experienced interventionalists. Recent instrumental and technical advances, however, including the development of both thin “floppy” and “stiff” wires, have resulted in a high success rate of CTO PCI. The technique of retrograde recanalization has allowed interventionalists at Mount Sinai to perform PCI on another 10–15 percent of patients, whose blockages were considered resistant to the antegrade approach.
These patients for retrograde recanalization return to the Cath Lab after they have healed completely from their first procedure attempt, usually about six to eight weeks later, for the second procedure. Using the retrograde approach, we penetrate the blockage from both ends to achieve recanalization. What makes this novel approach possible is the part played by collateral vessels. Normally very small and dormant, one or more collaterals are called into play when CTOs develop. They enlarge to let blood flow from an open coronary artery to an adjacent one or one farther downstream on the same artery, creating a detour around the blockage. It is a collateral that provides the “back door” through which the retrograde procedure can be successfully initiated.

Catheters are inserted over guidewires in both the groin and femoral arteries. The first and far smaller catheter approaches from the distal or back end, sliding the guidewire up the collateral until it reaches the blockage, which is typically softer and more penetrable at the distal end. The wire is manipulated delicately by the interventionalist until it creates a small opening in the dense and calcified proximal cap.

Once the blockage has been breached, a second wire is inserted through the still very slender channel from the antegrade end. A balloon and stent can then be delivered to the lesion, consistent with the direction of blood flow, to clear the channel lengthwise. Blood begins to flow in the artery again, and within 24 hours the collaterals, no longer needed for circulation, begin to go dormant again. The retrograde procedure takes about twice as long to perform as the antegrade; exceptional hand-eye coordination and a well-developed tactile sense are also required to negotiate the passageways.
Change in Plaque Composition and Plaque Regression

The effort to apply epidemiological approaches and methods to discovering the causes of cardiovascular disease and the means of prevention dates back to the 1960s. It is only in the last decade, however, that we have been able to state with confidence that we are achieving results in terms of a decrease in the number of heart attacks.

To illustrate, in 2005, in the Medicare population, 1,131 heart attacks occurred for every 100,000 patients. In 2010-2011, that rate was 866 heart attacks, a 23 percent decline. During the same period, a 31 percent reduction in sudden cardiac death was also observed. These figures suggest that disease stabilization and regression have become achievable goals through both preventive measures and aggressive cardiac care.

Man lives with atherosclerosis but dies from thrombosis, as the old axiom has it. If we can prevent plaque rupture, we can prolong life. To that end, over the last three years, several studies have documented plaque regression. Starting with ultrasound and other more novel imaging technologies, we can now characterize the main components of the substance that clogs the coronary arteries, also known as plaques. The four dangerous elements of plaques are a lipid core with a thin, fibrous cap; inflammation; eccentric growth; and neovascularization. The data suggest that we can intervene to change the composition from a dangerous phenotype — what we call vulnerable plaque — to a more, stable, ideally harmless substance.

At Mount Sinai we are finding that aggressive lipid-lowering therapy is reducing inflammation and increasing collagen production, leading to lower plaque volume and risk of rupture. We employ two novel imaging technologies, optical coherence tomography (OCT), a high-resolution wire-based intravascular imaging modality, and near-infrared (NIR) spectroscopy, a technique routinely used in the physical sciences to determine the chemical composition of substances, to quantify fibrous cap thickness and lipid core burden index (LCBI). In patients with severe obstructive disease, measurements taken before and after medication therapy have indicated improvements in hemodynamic severity based on fractional flow reserve along with reductions in LCBI. The reductions in LCBI can be extrapolated as a surrogate marker for reductions in inflammatory macrophage infiltration and apoptosis.

Recent data collected from a large pool of patients confirm the effectiveness of aggressive lipid-lowering therapy in reducing plaque volume, stopping eccentric growth, and inducing concentric regression. We have also seen in experimental human pathological data that large
“I cannot express how happy I’m feeling, and how grateful I am to God and to Dr. Moreno.”

Patient: Manuel de Jesus Tavares, 75-year-old man

Diagnosis: Angina, coronary atherosclerosis of native vessel, coronary atherosclerosis of bypass graft

Treatment: Coronary angiography, rotational atherectomy, placement of five DES

For Mr. Tavares, Dr. Pedro R. Moreno was literally the answer to a prayer. His mother died of heart disease at only 42, and five brothers passed before age of 50, but Mr. Tavares worked in construction and led an active life until he was 55, although he had diabetes, hypertension, and high cholesterol. Bypass surgery in September 1991 started a long, difficult stretch of years. “After the surgery, I didn’t feel well,” he said. “I couldn’t walk three blocks without gasping for breath, and I had constant pain in my legs.”

He saw a variety of doctors at city hospitals and clinics, without relief. He underwent angioplasty in 2007 but continued to suffer pain in his legs and his chest. His quality of life deteriorated to desperate levels. “I couldn’t lift anything — I could hardly walk across the room,” he said.

He underwent angioplasty again in June of 2011. He felt no better, but he remembers that the doctor told him, “You’ll have to learn to live with it.”

Almost defeated by this hopeless situation, Mr. Tavares sat down and wrote out a prayer, his “oracion a papá Dios nuestro señor,” in which he asked God to send a doctor who would restore him to health. He read the prayer faithfully every day. Then a neighbor told him about Dr. Pedro R. Moreno at Mount Sinai Hospital.

He saw Dr. Moreno in September. “He said, ‘I know I can help you.’” During a six-hour operation, Dr. Moreno performed rotational atherectomy and placed five stents in Mr. Tavares’ heart. Today, he is walking for exercise and maintaining a healthy diet.

plaques with a reduction in the lipid core exhibit significant reductions in neovascularization, lowering the risk of intraplaque hemorrhage.

Serial evaluations in humans with intravascular ultrasound-derived virtual histology (VH IVU.S.), used to assess composition and vulnerability of atherosclerotic lesions, have documented changes in plaque phenotype. Up to 75 percent of lesions exhibiting thin-cap fibroatheroma (vulnerable plaque) can be successfully converted into thick-cap (more stable plaque) within the first year of therapy. In addition, histological data from human carotid endarterectomy specimens have indicated significant reductions in macrophage infiltration in association with a simultaneous increase in smooth muscle cells after only three months of aggressive lipid-lowering therapy.

More recently, using OCT and NIR spectroscopy, we have identified neoatherosclerosis within coronary stents; here is another area on which to focus plaque regression that may result in lowering the incidence of late stent thrombosis.
Ambulatory PCI and Transradial Intervention

Patient satisfaction is a hot topic in health care today. In late 2012, Medicare will begin to take patient satisfaction scores into account when reimbursing hospitals. Hospitals are seeking to build customer loyalty; they want patients to return for further care and to recommend the institution to family and friends.

Ambulatory or “same-day” percutaneous intervention has gained attention nationwide as a patient pleaser. It’s obvious that the patient’s experience is more likely to be positive if he or she goes home the day of the procedure: no roommate; no shared bathroom; no night’s sleep interrupted by regular monitoring of vital signs; less inconvenience to family members; and of course less risk of falls in the night and other iatrogenic complications.

Mount Sinai has been way ahead of the curve in ambulatory PCI. Over the last decade, we have sent over 5,000 patients home the day of their procedure; in 2011, over 2,000 patients were discharged the same day, without compromising their recovery. A study published in the August 2010 issue of *JACC Cardiovascular Interventions*, entitled “Outcomes of Patients Discharged the Same Day Following Percutaneous Coronary Intervention,” reviewed the prospectively collected data on 2,400 patients discharged on the same day after uncomplicated PCI performed at Mount Sinai during a five-year period from April 2003 to March 2008. It concluded: “When appropriately selected, with strict adherence to the set protocol, same-day discharge after uncomplicated elective PCI is safe despite using femoral access in a wide spectrum of patients.”

In this study, 99.5 percent of the procedures were via the femoral approach (at the groin). Only 11 were performed transradially (at the wrist). In the last couple of years, however, not just at Mount Sinai but nationally, use of the transradial approach has skyrocketed.

The majority of patients undergoing diagnostic cardiac catheterization are middle-aged to elderly men, many of whom have developed prostate problems. Because the contrast dye used in the procedure is a diuretic, patients need to void very soon after the procedure is completed. With the femoral approach, patients must remain prone to urinate. In this unnatural position, voiding is uncomfortable, difficult, and often impossible for men, and even for women. A temporary catheter may be required, which can lead to further complications.

With the transradial approach, on the other hand, patients can urinate in the normal way; they can sit up, eat a meal, watch television, and generally enjoy a more comfortable post-operative experience. It is ideal for obese patients and patients with peripheral vascular disease or prior
“The beauty of it is that I can have the blockage opened and go home to Yonkers the same day.”

Patient: Nader Sayegh, 59-year-old man
Diagnosis: Angina, coronary atherosclerosis of native vessel
Treatment: Coronary angiography, left ventriculography, placement of DES

“Unfortunately, I have a cardiovascular condition where my arteries become blocked. I’m fortunate, however, to be able to put myself in the hands of top-level medical professionals like those at Mount Sinai. I have received catheterization and angioplasty here a few times before, and the beauty of it is that I can have the blockage opened and go home to Yonkers the same day.

“The last procedure I had here, in December 2011, Dr. Michael Kim recommended a different entry point for the catheter – the wrist instead of the groin. He said my recovery would be even quicker, and it was. With the groin entry, you have to be careful moving the wrong way, and you have to watch for bleeding. The entry site at the wrist is much easier for the nurses to monitor, and I found the whole experience to be even more positive than my previous catheterizations.

“There are five medical doctors in my family, so I guess you can say that I have high standards, but Mount Sinai stands tall among the competition, as does Dr. Kim. My condition is chronic, so future procedures are likely. Mount Sinai will always be my hospital.”

complications from femoral artery catheterizations. Studies have shown that bleeding at the access site and other complications are less likely, which means that same-day discharge is more likely. And a patient who goes home to sleep in his or her own bed that night is much more likely to rate the PCI experience a positive one.

And what about costs? Cutting costs by curtailing superfluous spending is another hot topic in healthcare today. There are significant costs associated with an overnight hospital stay, and if that stay is unnecessary it not only wastes money but also contributes to a more negatively perceived patient experience. Less unnecessary care is better care.

Same-discharge discharge for appropriate patients who have undergone percutaneous coronary intervention has helped us to achieve recognition as a center of excellence in PCI, with physicians and administrators coming to Mount Sinai from all over the country to study our program. Our new emphasis on the transradial approach for appropriate patients — has contributed not only to a higher rate of same-day discharges but also to patient satisfaction with the PCI experience.

*The authors were Mehul Patel, MD, Michael Kim, MD, Rucha Karajgikar, MBBS, Visali Kodali, MD, Dheeraj Kaplish, MBBS, Paul Lee, MD, Pedro Moreno, MD, Prakash Krishnan, MD, Samin K. Sharma, MD, and Annapoorna S. Kini, MD, all of the Cardiac Catheterization Laboratory of Mount Sinai’s Zena and Michael A. Wiener Cardiovascular Institute.
### Risk Factors for PVD: Framingham Heart Study

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The Importance of Screening for PAD

Screening patients to diagnose indolent disease is an essential part of any practice. Whether it is screening for breast or prostate cancer, screening has been shown to reduce morbidity and mortality. Screening for peripheral arterial disease (PAD) is essential in the early diagnosis of atherosclerotic cardiovascular disease. Early diagnosis and treatment can prevent the late manifestations of advanced disease such as myocardial infarction, stroke, renal failure and limb loss. This case study is an example of how an effective screening program can save lives and prevent adverse outcomes.

A 71-year-old male, a former smoker, with a history of hyperlipidemia, hypertension, Type II diabetes and peripheral arterial disease was referred for evaluation of abnormal ABI/PVR, (.86 on the right leg and .84 in the left leg). Pertinent findings on exam were a soft bruit in the right and left carotid. All labs including the patient HB A1c, cholesterol panel, and vitals were within normal limits.

Ultrasound revealed bilateral critical carotid artery stenosis (CAS), and a CT angiogram confirmed high-grade CAS amenable to surgery. The patient had no complaints of chest pain, shortness of breath or history of TIA (transient ischemic attacks) and stroke.

Upon the diagnosis of CAS, the patient was worked up for heart disease with an echocardiogram (ECG) and stress test. His ejection fraction was 30 percent and a stress test was positive for extensive ischemia in the anterolateral and inferior walls. Cardiac catheterization revealed severe left main and three-vessel coronary disease. The patient underwent a successful carotid stent procedure and one month later a 3-vessel coronary artery bypass. This patient exemplifies the importance of screening for PAD. He has all the risk factors for advanced atherosclerosis — male gender, ex-smoker, diabetic, hyperlipidemic, hypertensive and history of peripheral arterial disease. The abnormal ABI/PVR was the first objective evidence of atherosclerosis. This led to further identifying a carotid bruit and diminished pulses and eventually to the diagnosis and treatment of his severe carotid artery stenosis and 3-vessel coronary artery disease.

This patient is the beneficiary of an effective PAD screening program that illustrates the systemic nature of atherosclerosis. The simple ABI/PVR diagnosed the presence of silent PAD. This led to the diagnosis of critical carotid and coronary artery disease and the timely management to prevent an adverse outcome.
“I’m very grateful to Dr. Krishnan and his staff who took such excellent care of me.”

**Patient:** Rafael Beato, 71-year-old man  
**Diagnosis:** Carotid artery stenosis, severe coronary artery disease  
**Treatment:** Placement of two carotid artery stents, coronary artery bypass graft surgery

“I was feeling okay, although because I lost my left leg below the knee to diabetes, I don’t ever really exert myself. I was very surprised when a routine screening at my regular physician’s office started me down the road to open heart surgery at Mount Sinai Hospital! First, a month or so before the open heart, I had a couple of stents put in my carotid arteries, also at Mount Sinai.

“My doctor, Prakash Krishnan, was great. Of course, I was alarmed when he recommended test after test. I’d never worried about my heart before. But Dr. Krishnan and his staff explained everything, step by step, test after test. They allayed my fears completely. Both procedures and my recovery went better than I expected. And now I know what it’s like to feel well.

“I’m very grateful to Dr. Krishnan and his staff who took such excellent care of me. When I talk to anyone with a heart problem, I tell them to make an appointment with one of the heart doctors at Mount Sinai.”

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**Atherothrombosis – Symptomatic Atherosclerosis in CAPRIE (overlap between PAD, CAD and CVD)**

CAPRIE¹ (n = 19,185)

- Cerebrovascular Disease (CVD): 24.6%
- Coronary Artery Disease (CAD): 29.9%
- Peripheral Arterial Disease (PAD): 19.2%
- Other: 4.6%


**ABI – inverse relationship with 5-year risk of cardiovascular events and death**

- 2.5
- 1
- 1.5
- 1
- .5
- 0

0 .2 .4 .6 .8 1

- 10.2% relative risk increase per 0.1 decrease in ABI  
(p = 0.041)
Cardiovascular Innovations on the Horizon for 2012

Catheter-Based Renal Sympathetic Denervation for Resistant Hypertension: SIMPLICITY III Trial

Late in 2011, Mount Sinai Medical Center was given approval to participate in a study of a treatment modality for patients with resistant hypertension that may rejuvenate physicians’ interest in this large and difficult-to-treat population. Resistant hypertension is defined as blood pressure that remains high despite treatment with three medications, confirmed by a home blood pressure log and ambulatory blood pressure monitoring.

There is a new understanding that resistant hypertension might be related to a form of blood pressure that is propagated by nerve stimulation, particularly through an abnormal nerve circuit that connects the brain with the nerves around the kidney arteries.

Patients undergo catheterization and angiography to ascertain that there are no blockages in the renal arteries. Then a form of radiofrequency energy is applied via catheter to ablate the nerves involved in the abnormal circuit. Preliminary results in experiments as well as human studies indicate that the treatment is safe, and results are encouraging regarding hypertension control. The treatment appears to offer new hope for patients with this recalcitrant condition.

The Carotid Stent Proximal Embolic Protective System: CHOICE Trial

Carotid artery stenosis is potentially associated with strokes and may already have caused strokes or mini-ischemic attacks. The method of screening for these blockages is to perform ultrasound followed by an angiogram to verify the findings. The artery is then opened with a balloon and a stent is placed in the artery, but there is one critical requirement: traveling of any fractures or microfractures, either clot or plaque, from the blockage to the brain must be prevented or minimized.

Traditionally, a tiny umbrella filter is opened above the blockage to capture any debris. After the stent is set in place, the filter is removed. While it is possible that with this method debris might find a branch in the artery or the filter itself might cause a fracture, the carotid stent proximal embolic protective system being studied here at Mount Sinai appears to offer 100 percent protection.

The system works by taking advantage of communication between the left
“I trusted Dr. Dangas to take good care of me and he didn’t let me down.”

Patient: Louise Schrom, 87-year-old woman
Diagnosis: Coronary atherosclerosis of native vessel, acute diastolic heart failure, aortic valve disease
Treatment: Catheterization, balloon aortic valvuloplasty

“I’ve had a bad heart for a number of years, but a few months ago I noticed that I was out of breath just walking a few steps inside my home. Sometimes I felt my heart fluttering — palpitations, they call it. So I went to see my regular doctor, and he sent me to Dr. Dangas at Mount Sinai.

“The first thing I said to Dr. Dangas and his team was, ‘I don’t want you to open my chest.’ The idea of open-heart surgery is terrifying to me, although I know they do it all the time. So they put me through many tests, and Dr. Dangas told me that one of my valves was very, very bad — dangerously closed, he said. But he told me he could treat me without opening my chest. ‘I don’t know anything about that,’ I told him, ‘so I’m leaving it in your hands.’

“So I was admitted to Mount Sinai, and I had the procedures, and I have to say the experience was very positive. Everybody at the hospital was really, really wonderful, especially Dr. Dangas. I trusted him to take good care of me and he didn’t let me down.”

and right sides of the brain. When blood flow is occluded by a balloon in the main artery before the blockage and another balloon in a side branch, the brain automatically reverses the flow so that any loose particles are sucked into the system.

Automated Kidney Protection During Angiographic Procedures: RENALGUARD Trial

During cases involving patients with significant heart disease and perhaps renal failure as well, a concern for the interventional cardiologist has been protecting them from the effects of the contrast medium administered intravenously. Keeping the patient adequately hydrated during and after the procedure is absolutely essential, but calculating how much dye has been used, how much urine has been produced, and how much fluid needs to be replenished is simply an impossible task for the nurse. A new system now performs the calculations and replaces the fluids automatically. It is used in conjunction with a loop diuretic to produce high urine flow rates; the thinking is that the diuretic promotes more rapid transit of the potentially toxic dyes through the nephrons.
The Role of Genetic Testing in the Cardiac Cath Lab

Effective platelet inhibition is paramount in the management of patients with acute coronary syndrome (ACS). Clopidogrel has provided significant reductions in major cardiovascular events in patients with ACS, particularly those treated by percutaneous coronary intervention (PCI). However, recent data from clinical trials have demonstrated that not all patients exhibit the same antiplatelet effect from clopidogrel and those patients with a low or reduced clopidogrel response may be at an increased risk of cardiovascular events following PCI for ACS.

There are a number of reasons why patients can have reduced responsiveness to clopidogrel which include medication noncompliance, drug-drug interactions and other clinical variables such as diabetes mellitus and chronic kidney disease. Beyond that, recent large-scale studies have suggested that there is also a genetic predisposition to reduced clopidogrel responsiveness.

In retrospective analyses of trials involving patients who have developed stent thrombosis after PCI, a specific genetic allele has been discovered that confers reduced responsiveness to clopidogrel: the cytochrome P450 2C19 *2 allelic polymorphism (abbreviated CYP2C19 *2). Carriers of this dangerous allele have demonstrated lower levels of the active clopidogrel metabolite and increased platelet activity after stent implantation. Simply put, in these patients, clopidogrel is not fully metabolized and as a consequence their platelets remain sticky; they aggregate, or stick to each other and to the implanted stent, potentially resulting in stent thrombosis.

Studies suggest that up to 25 to 30 percent of the general population is heterozygous for the CYP2C19*2 allele; that is, they received one dangerous allele from one parent and a normal allele from the other parent. Heterozygous carriers seem to be at a higher risk for reduced responsiveness to platelet inhibition therapy compared to those patients that received both normal alleles from both parents resulting in a normal functioning CYP2C19 enzyme. Individuals who are homozygous for CYP2C19 *2 allele, having received the dangerous allele from both parents, represent only 2 to 3 percent of the population but appear to be at a much higher risk for stent thrombosis.

Knowing this information, should we be testing all patients that come to the Cath Lab for this potentially dangerous genetic allele before getting a coronary stent? Unfortunately, the cost and the time it takes to obtain the results are two barriers preventing routine genetic testing in the Cath Lab. In a research project done in our Cath Lab, however, we were able to
obtain genetic analyses among patients receiving a coronary stent before they were discharged from the hospital and then, if indicated, alter their antiplatelet therapy to a more potent medication called prasugrel. Like clopidogrel, prasugrel is a prodrug but more potent and able to overcome the genetic resistance.

Our project showed that we can obtain the results of genetic testing in a timely manner, and as a result, we are able offer a personalized approach to antiplatelet therapy among select patients undergoing a PCI for ACS at the Mount Sinai Cath Lab.
Imagine the excitement of your freshman year in college turning to fear when you suddenly develop heart failure. That is what happened to Vonn O’Brien. Severely short of breath, he was admitted to Mount Sinai Medical Center where his heart was discovered to be irreversibly failing. His best option was a heart transplant, but he couldn’t wait that long. Instead, Vonn received the HeartMate II, one of the latest generation of left ventricular assist devices, or LVADs. Implanted by cardiothoracic surgeon Anelechi Anyanwu, MD, this miniaturized pump spins like a turbine at 9,000 to 10,000 RPM, generating enough blood flow to support the heart and circulation.

Over the next two weeks, Mr. O’Brien recuperated in the hospital before returning home. He went back to school in the fall. Little more than one year after receiving his LVAD, through the generosity of a deceased donor’s family, Mr. O’Brien received his heart transplant. He is home once again, playing his saxophone and waiting to rejoin his classmates for the start of the new semester.

Cases like Mr. O’Brien’s are not unusual for the Advanced Heart Failure and Cardiac Transplant team. Last year this program cared for hundreds of patients in the final stages of heart failure. With their pediatric colleagues, they performed 29 heart transplants and implanted 48 ventricular assist devices, 34 of which were HeartMate IIs. The clinical outcomes were impressive. Hospital length of stay averaged 16 days after LVAD placement. Both short-term and long-term survival exceeded national averages. Patient self-reported quality of life was excellent, with most experiencing little or no impairment in the performance of their daily activities.

As impressive as these technologies may be, next-generation LVADs, currently in production, are even smaller and can be implanted through minimally invasive approaches. Pumps like the HeartWare HVAD can be contained entirely within the pericardium, simplifying the surgery and facilitating healing. Another, from Circulite, is the size of a double-A battery and can generate almost 3 liters of blood flow per minute, offering the heart plenty of assistance. Other improvements soon to be incorporated into the current devices include a fully implantable pump that doesn’t require a driveline exiting the body. Power will be delivered across the skin to an implanted battery that drives the device. Patients will have the freedom to bathe and even go swimming.
“Everybody knows my name here, so I’m always glad to come back.”

**Patient:** Barrington Binger  
62-year-old man

**Diagnosis:** Congestive heart failure

**Procedure:** LVAD as bridge followed by heart transplant; follow-up endomyocardial biopsy

“I have always exercised, but in the fall of 2010 I was often too tired to put on my jogging shoes, and my feet were swollen. I was seen at a Long Island hospital and sent to Mount Sinai. When I saw Dr. Pinney he diagnosed me with severe congestive heart failure and admitted me on the spot.

“As Dr. Pinney explained it, my left ventricle wasn’t doing an adequate job of pumping out the blood. A left ventricular assist device, or LVAD, was implanted in my abdomen, with a wire coming out my side that was attached to a battery pack.

“When they mentioned a heart transplant, my reaction was, ‘No way.’ But even though I was feeling better with the LVAD, I knew that it was rarely a permanent solution, so I agreed to go on the transplant list.

“On June 14, 2011, they called to tell me they had my heart. I went right into the operating room, with no time to be anxious. The procedure and my recovery went smoothly. I’m feeling well, although I don’t push myself. I lift some weights at home, that’s all.

“Rejection is always a concern with a transplant, so I have regular appointments for biopsies, performed by Dr. Pinney. Everybody knows my name here, so I’m always glad to come back. I am very fortunate to have found such an excellent hospital and such excellent doctors.”

At Mount Sinai, clinical trials of regenerative therapies are under way to discover new techniques to repair injured hearts. In the future, LVAD-supported patients may receive either gene therapy or stem cells to improve heart function enough to safely remove the LVAD and eliminate the need for transplantation. While these trials are in their infancy, they offer promise of returning patients to an active lifestyle with their own hearts whole once again.
Transcatheter Pulmonary Valve Replacement in Congenital Heart Disease

Surgically placed conduits from the right ventricle to the pulmonary artery are used to palliate several forms of congenital heart disease. Over time, however, these conduits become dysfunctional, developing stenosis, regurgitation, or both. Bioprosthetic valves suffer the same fate. Conduit stenosis imposes pressure load on the right ventricle, resulting in hypertrophy, systolic and diastolic dysfunction, and eventually right ventricular failure. While pulmonary regurgitation was considered relatively benign, recent studies have shown that this condition leads to right ventricular dilation, systolic and diastolic dysfunction, and ultimately irreversible right ventricular damage. Because the risk of complications increases with each subsequent revision, prolonging the life of the conduit has clear advantages.

In 2000, Philipp Bonhoeffer, MD, performed the first-in-human replacement of a pulmonary valve using a catheter-based system. This led to the development of the Melody® Transcatheter Pulmonary Valve (Medtronic, Inc.), fashioned from a bovine internal jugular valve mounted on a platinum-iridium stent. It is the first transcatheter device to earn FDA approval (as a humanitarian device).

The delivery system is an adaptation of the conventional balloon-in-balloon catheter used to implant large-diameter stents in patients with congenital heart disease, with the addition of a tapered distal shaft (the “carrot”) and a retractable sheath to protect the valve as it is advanced into position. The outer diameter is relatively large (22 French), but most patients eight years old and above can tolerate this via a femoral venous approach.

Major complications occur infrequently. There is approximately a 1 percent risk of conduit rupture if stenotic conduits are expanded too aggressively, but this can usually be managed percutaneously since after deployment the Melody valve functions as a covered stent. Coronary artery compression can occur if the conduit courses adjacent to a coronary artery, particularly in patients who have undergone the Ross procedure, but experienced physicians know to carefully assess the course of the coronary arteries before expanding a stent in the RVOT. In rare circumstances, the Melody valve cannot be deployed because of the risk of
“He explained everything, and he made me feel totally calm and confident.”

**Patient:** Stephanie Diaz, 21-year-old woman  
**Diagnosis:** Congenital pulmonary stenosis  
**Treatment:** Placement of Melody Transcatheter Pulmonary Valve

Stephanie is a 21-year-old student in New York. She was born with severe pulmonary valve stenosis. In 1990, balloon dilation for pulmonary stenosis was not yet possible, and she underwent heart surgery to open the valve. Stephanie did well for many years but had progressive pulmonary insufficiency and her right ventricle became severely enlarged. At age 19 years, she had surgical pulmonary valve replacement at another hospital. "At first I felt really good, but it didn’t last. Within two years I could scarcely walk a block without being out of breath, and I was having heart palpitations. I felt worse than I had before the surgery. Then I found Dr. Fuster, who introduced me to Dr. Love.”

After non-invasive testing, it was determined that Stephanie had moderate pulmonary valve stenosis and moderate to severe pulmonary insufficiency. The surgically placed valve wasn’t working.

"Dr. Love told me that they were going to give me another valve, and that it wouldn’t be open-heart surgery but would be minimally invasive using a catheter. That was good news. He explained everything, and he made me feel totally calm and confident.”

In October 2011, Stephanie underwent the first catheter-delivered pulmonary valve replacement at Mount Sinai using the newly FDA approved Melody Transcatheter Pulmonary Valve.

"The procedure was quick, and I spent only one night in the hospital. The next week I went back to school.”

"I feel great now, and it’s thanks to Dr. Love. I was one of the first to receive this valve, but I’m sure Dr. Love has gone on to perform the procedure many more times, helping young people like me. I love Dr. Love.”

coronary artery impingement. Long-term follow-up has shown freedom from reintervention of 95 percent at one year and 76 percent at four years.\(^4\) If the valve should become dysfunctional over time, a second Melody valve can be implanted inside the first.

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Mount Sinai Heart Outcomes Center

The mission of the Interventional Cardiovascular Research and Clinical Trials group at Mount Sinai is to encourage, support, and evaluate innovative ideas in cardiovascular medicine. Our group participates as a leading national and international resource in the gathering, analysis and dissemination of information pertaining to the prevention, diagnosis and treatment of cardiovascular disease.

Active in prominent clinical trials as well as investigator initiated studies, our research group is equipped with an excellent team of experienced research personnel that provides a full spectrum of clinical management services. The ability to combine medical knowledge with proprietary clinical trial management software puts us in an exceptional position to ensure the highest level of data integrity for each study. This unique system for complete trial management results in efficient planning, tracking, and execution of projects. We are currently conducting a multitude of studies investigating the efficacy of different types of stents, the effect of non-adherence on clinical outcomes, and drug efficacy associated with certain procedures.

In addition to these studies, our group has developed a new module-based relational database for the Mount Sinai Heart Outcomes Center that will allow patient-centered research for all subdivisions of Mount Sinai Heart. Programmers in our group created this database, which is a milestone due to the fact that it is the result of the first integration of different information technology (IT) divisions at Mount Sinai. The database establishes a prospective mechanism for the review of clinical outcomes following a cardiac diagnostic or interventional procedure. Utilizing standardized definitions to document information related to clinical reports and patient outcomes will allow for contribution of this data to national data repositories, including the National Cardiovascular Data Registry. Quality assurance and quality control measures are in place to ensure the integrity of the data, and we follow up with patients in order to gain a better understanding of the long-term endpoints associated with hospital procedures and medications. Improved capacity to conduct comparative effectiveness research and data-driven research initiatives are examples of the ways in which reporting to national registries will enhance our group’s ability to conduct innovative research.
The responsibility to collect, review, and analyze our patient experience and outcomes, both in hospital and after discharge to their home environment, enhances the fundamental goal of entirely personal and compassionate patient care. As a participant in efforts to define and solve health problems in population groups and communities through the development of scientific knowledge, our group at Mount Sinai seeks to provide new insights for future therapies. Additionally, we aim to expand to the areas of global cardiovascular diseases as well as broaden the data center capacity as the designated center for innovative outcomes research with multicenter U.S. and international sites.
Peripheral Artery Disease Screening

Individuals identified at risk for peripheral artery disease (PAD) in epidemiological studies include adults younger than 50 with diabetes and another atherosclerosis risk factor such as smoking, dyslipidemia, hypertension or hyperhomocysteinemia; adults 50 to 69 years old with a history of smoking or diabetes; and adults age 70 and older. Also at risk are those with leg symptoms on exertion, ischemic leg pain, abnormal lower-extremity pulse examination or known atherosclerotic coronary, carotid or renal disease.

History and vascular physical assessment are the initial steps in diagnosing peripheral arterial disease, learning of any history of exertional limitations of the lower-extremity muscles or walking impairment, described as fatigue, aching, numbness or pain in the buttocks, thigh, calf or foot. Other pertinent history should include any poorly healing or nonhealing wounds of the legs or feet, any pain at rest localized to the lower leg or foot and its association with the upright or recumbent positions, postprandial abdominal pain that reproducibly is provoked by eating and is associated with weight loss, and a first-degree relative with an abdominal aortic aneurysm.

The examining doctor should note any asymmetry with interarm blood pressure and palpation of carotid pulses, recording of carotid upstroke and amplitude, and presence of bruit should be noted. Palpation of pulses at the brachial, radial, ulnar, femoral, popliteal, dorsalis pedis, and posterior tibial sites should be routine. The shoes and socks should be removed and the feet should be inspected, noting color, temperature, and the integrity of the skin, including the presence of ulcerations. Additional findings such as distal hair loss, trophic skin changes and hypertrophic nails, should be sought and recorded.

Noninvasive diagnostic testing provides a set of assessment tools to evaluate the status and/or severity of PAD and permits the creation of a therapeutic plan for the specific clinical presentation.

<table>
<thead>
<tr>
<th>Clinical Presentation</th>
<th>Noninvasive Vascular Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymptomatic lower-extremity PAD</td>
<td>Ankle-brachial index (ABI)</td>
</tr>
<tr>
<td>Claudication</td>
<td>ABI, pulse volume recording (PVR) or segmental pressures</td>
</tr>
<tr>
<td></td>
<td>Duplex ultrasound</td>
</tr>
<tr>
<td></td>
<td>Exercise test with ABI to assess functional status</td>
</tr>
<tr>
<td>Possible pseudoclaudication</td>
<td>Exercise test with ABI</td>
</tr>
<tr>
<td>Postoperative vein graft follow-up</td>
<td>Duplex ultrasound</td>
</tr>
<tr>
<td>Femoral pseudoaneurysm; iliac or popliteal</td>
<td>Duplex ultrasound</td>
</tr>
<tr>
<td>aneurysm</td>
<td></td>
</tr>
<tr>
<td>Suspected aortic aneurysm; serial abdominal</td>
<td>Abdominal ultrasound, computed Tomographic angiography (CTA)</td>
</tr>
<tr>
<td>abdominal aortic aneurysm (AAA)</td>
<td>or magnetic resonance angiography (MRA)</td>
</tr>
<tr>
<td>Candidate for revascularization</td>
<td>Duplex ultrasound, MRA, or CTA</td>
</tr>
</tbody>
</table>
The Role of Nurse Practitioners in the CoreValve U.S. Pivotal Trial: Transcatheter Aortic Valve Implantation (TAVI)

Transcatheter aortic valve implantation (TAVI) has emerged as a promising treatment for patients with severe, symptomatic aortic stenosis who have a high or prohibitive risk for surgical aortic valve replacement (SAVR). Mount Sinai has been involved in the CoreValve Trial since December 2010, performing the first TAVI procedure in the U.S. with this system. Nurse practitioners (NPs) involved in this multidisciplinary project play an integral role and are required to complete a training protocol with Medtronic. This specialized training provides gaining explicit knowledge of the trial, the device, objectives and protocols.

The NP’s primary role is the screening evaluation and pre-procedural care of patients. We work closely with the research coordinator in the workup of potential candidates for the trial and with the patients once they are enrolled. We have developed a systematic approach which enhances continuity and the development of a rapport with the patients and family.

Once a patient has been identified as a potential candidate for the CoreValve trial, the patient and family meet with the NP and research coordinator to learn more. A thorough history and physical exam are performed and prior diagnostic tests and procedures are evaluated. Communication with the patient’s primary cardiologist is ongoing at this time. Next, the required diagnostic and laboratory tests to are ordered and scheduled to evaluate the patient. Findings on the screening tests that warrant further imaging and/or consultation must be addressed. Once the diagnostic screening workup and all required consultations have been completed, a date is chosen to present the patient to the screening committee.

If the patient is enrolled, a date for the procedure is established, and admission is scheduled. Upon admission, all pre-procedure orders are instituted and informed consent is obtained. The research coordinator and the NP communicate with the nurses and charge nurse of the Cath Lab to facilitate the flow and efficiency on the day of the procedure. NPs coordinate with the receiving unit, either the cardiothoracic ICU or the CCU, to prepare for the patient’s arrival. Post-procedure, the NP rounds on the patients with the research coordinator daily until discharge.

Communication with the patients is maintained after discharge, and they are instructed to notify us of any issues and/or concerns. The patients return for their follow-up assessments according to the research protocol. This team approach has led to positive outcomes and a steadily increasing volume.
RESEARCH AND CLINICAL TRIALS

**Top 10 Major Publications: Mount Sinai Cardiac Cath Lab**


   **Clinical Implications:** This observational study was the first report in the literature to document that minor post-procedure enzyme elevation is common after otherwise successful PCI and is not associated with any higher mortality at 12-15 months follow-up. We also established with careful follow-up that patients with elevated CK-MB but declining value can safely be discharged home without any untoward events.


   **Clinical Implications:** There are various techniques for PCI of large bifurcation coronary lesions, but none of them is perfect. We invented a simplified bifurcation technique of placing two stents side-by-side with excellent short-term outcomes and lower restenosis (<5%) at 15 months of follow-up.


   **Clinical Implications:** This publication challenges the common practice of deferring bivalirudin use in cases of potential coronary perforation (largely due to lack of an antidote). Our systematic analysis showed that guidewire-induced coronary perforation if occurring with bivalirudin use had a benign course compared to occurring with heparin. This can simply be explained on the basis of short bivalirudin half life.


   **Clinical Implications:** This largest series of same-day discharges of PCI patients (n=2,400) provided the system process for safe discharge of selected PCI patients with extremely low (<1%) major or minor cardiovascular and bleeding events at 30 days.


   **Clinical Implications:** This publication compared the outcomes of LV assist devices, Impella versus TandemHeart, in 68 high-risk PCIs at Mount Sinai Hospital and found Impella to be a faster and equally effective LV assist device with similar vascular and ischemic complications.

**Clinical Implications:** This meta-analysis of 13 randomized trials involving over 17,000 patients showed that XIENCE V DES has the lowest stent thrombosis compared to any other DES: Cypher, Taxus, Endeavor, or Resolute. Also, stent thrombosis was not related to DAPT interruption after 6 months. These attributes have made XIENCE V one of the most commonly used DES in the USA.


**Clinical Implications:** This landmark histopathological study showed that neovascularization and intra-plaque hemorrhages are more common in diabetics than in nondiabetics. This phenomenon may cause rapid plaque progression in diabetic patients and can explain high plaque rupture in these patients, causing ACS.


**Clinical Implications:** These updated PCI guidelines provided the framework for the choices of revascularization in various angiographic categories, and elevated ULM PCI status to IIA or IIB based on clinical conditions and expected procedural results. Guidelines also made Heart Team discussion mandatory in complex CAD management as class I indication.


**Clinical Implications:** This landmark study reported that one in seven PCI patients were readmitted within 30 days, and half were for cardiac reasons. Hence improving overall care of PCI patients may reduce this alarmingly high readmission rate and will significantly reduce health care costs.


**Clinical Implications:** This presentation of 13,752 patients with 34.6 percent female reported female gender to be an adverse prognostic factor compared to male patients after PCI. Hence extra care should be exercised in overall management of female PCI patients.

Mount Sinai Heart Cardiac Cath Lab has advanced the field of interventional cardiology by establishing appropriateness of interventional procedures and improving procedural outcomes by conducting and participating in well-designed clinical research trials and the publication of major clinical findings based on an extensive interventional database of over 38,000 patients.
## TOP 10 KEY CLINICAL TRIALS

Among the 35 clinical research trials being conducted currently at the MSH Cath Lab, following are the top 10 trials, which are likely to have an important impact in the field of interventional cardiology.

<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>
</tr>
</thead>
<tbody>
<tr>
<td>FREEDOM Trial</td>
<td>Randomized trial comparing CABG to PCI in diabetics with multivessel disease. Evaluating whether PCI with DES is more or less effective than existing standard of care CABG. Multicenter, two-arm, open label prospective randomized superiority trial with equal allocation of 3 years' duration.</td>
<td>National Heart, Lung and Blood Institute (NHLBI)</td>
<td>S. Sharma</td>
<td>2,058 (global)</td>
<td>Completed/71 subjects enrolled, 35 PCI / 36 CABG</td>
</tr>
<tr>
<td>Impella PROTECT II Trial</td>
<td>Prospective, multicenter randomized controlled trial of the Impella® Recover® LP 2.5 System versus intra-aortic balloon pump (IABP) in patients undergoing non-emergent high-risk PCI</td>
<td>Abiomed</td>
<td>S. Sharma</td>
<td>650 (USA)/ terminated after 465 patients</td>
<td>Completed/25 subjects enrolled</td>
</tr>
<tr>
<td>CoreValve U.S. Pivotal Trial</td>
<td>Trial of CoreValve® in patients with severe aortic stenosis, who are at high risk or extreme risk for cardiac surgery</td>
<td>Medtronic</td>
<td>S. Sharma</td>
<td>1,350 (USA)/ 42 centers</td>
<td>Ongoing /33 subjects enrolled</td>
</tr>
<tr>
<td>BOSS Trial</td>
<td>Evaluation of sodium bicarbonate to reduce the incidence of contrast-induced nephropathy (CIN) in patients with chronic kidney disease (CKD) who are undergoing angiography and interventions</td>
<td>MD Scientific</td>
<td>M. Kim</td>
<td>570 (USA)/ 60 centers</td>
<td>Ongoing/12 subjects enrolled</td>
</tr>
<tr>
<td>COLOR Registry</td>
<td>Chemometric Observations of LCP of Interest in Native Coronary Arteries Registry using LipiScan Coronary Imaging System</td>
<td>InfraReDx</td>
<td>A. Kini</td>
<td>2,000 (USA)/ 50 centers</td>
<td>Ongoing/155 subjects enrolled</td>
</tr>
<tr>
<td>Study Title</td>
<td>Study Details</td>
<td>Sponsor</td>
<td>Principal Investigator(s)</td>
<td>Target Enrollment and Study Sites</td>
<td>Current Status/ Enrollment at MSH</td>
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<tr>
<td>YELLOW Trial</td>
<td>Reduction in Yellow Plaque by Aggressive Lipid LOWering Therapy</td>
<td>InfraReDx, MSSM</td>
<td>A. Kini</td>
<td>87/single center, MSSM</td>
<td>Completed/all subjects enrolled</td>
</tr>
<tr>
<td>Tryton Side Branch Stent Trial</td>
<td>Comparison of Tryton Stent in side branch with DES in main vessel to PTCA in side branch with DES in main vessel</td>
<td>Tryton Medical</td>
<td>S. Sharma</td>
<td>700 (USA)/ 75 centers</td>
<td>Ongoing/17 subjects enrolled</td>
</tr>
<tr>
<td>EXPERT-CTO Trial</td>
<td>Evaluation of XIENCE V Coronary Stent, performance and technique in chronic total occlusion; evaluation of success of HT PROGRESS and HT PILOT guidewires</td>
<td>Abbott Vascular</td>
<td>A. Kini</td>
<td>240(USA)/ 40 centers</td>
<td>Ongoing/12 subjects enrolled</td>
</tr>
<tr>
<td>CHOICE Trial</td>
<td>Evaluation of outcomes of carotid stenting for high-surgical-risk patients through collection of clinical evidence</td>
<td>Abbott Vascular</td>
<td>P. Krishnan</td>
<td>18,000 (global)/ post-market surveillance</td>
<td>Ongoing/12 subjects enrolled</td>
</tr>
<tr>
<td>LEVANT 2 Trial</td>
<td>Study of Lutonix Moxy drug-coated balloon, catheter vs. standard PTA, catheter in treatment of femoropopliteal arterial disease</td>
<td>Lutonix</td>
<td>P. Krishnan</td>
<td>400 (global)/ 184 centers</td>
<td>Ongoing/21 subjects enrolled</td>
</tr>
</tbody>
</table>
Samin K. Sharma, MD, FSCAI, FACC
Director, Clinical & Interventional Cardiology
President, Mount Sinai Heart Network
Dean, International Clinical Affiliations
Zena & Michael A. Wiener Professor of Medicine

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MBBS: S.M.S Medical College Jaipur, India
Residency, Internal Medicine: New York Infirmary- Beekman Downtown Hospital, NY
Fellowship, Cardiology: City Hospital Center at Elmhurst, NY
Fellowship, Interventional Cardiology: Mount Sinai Hospital, NY

Dr. Samin K. Sharma is well known for complex coronary interventions, performing over 1,500 interventions a year (the highest in the country) with an extremely low complication rate. According to New York State Department of Health reports, he had the highest angioplasty success rate (lowest mortality <0.2%) in the entire group of interventional cardiologists in New York State from 1994 to 2003 and from 2007 to 2008, a remarkable feat considering the complexity of cases referred. Dr. Sharma has authored over 130 articles, over 300 abstracts and 12 book chapters and has been the editor of Cardiology Clinic’s December 2006 and February 2010 issues. His publications focus primarily on innovative procedural techniques to improve interventional success and reduce complication rates. He has been dubbed the “master of the Rotablator” and has been regularly featured on national and local TV and in various newspapers and magazines such as Newsday, Newsweek, New York Times, New York Post, Forbes, Wall Street Journal, Barron’s, Daily News, Washington Post, New York Resident, the New York Sun, New York Magazine,Earthtimes, India Abroad, and India Today. Dr. Sharma also has passion for teaching; his fellows presented him with the Simon Dack award in 2000 and the Fellows Advocate Award in 2009. Every year a large number of interventionalists learn from Dr. Sharma’s masterful teaching to become safe operators. Dr. Sharma has been the recipient of numerous awards for excellence, including: the 2011 Ellis Island Medal of Honor, the 2011 American Heart Association Achievement in Cardiovascular Science & Medicine Award, the 2011 Physician of the Year award from the American Association of Physicians of Indian Origin (AAPI), 2003-2007 Best Doctors, 2008-2011 Super Doctors, and the 2007 Jacobi Medallion Award and the 2007 Physician of the Year Award at Mount Sinai Hospital. New York Governor George Pataki presented Dr. Sharma with the Governor’s Excellence Award on May 23, 2006. Dr. Sharma has had the privilege of performing invasive procedures on various heads of state. He has served on the Cardiac Advisory Board of New York State since 2004. He was then appointed as an attending at Mount Sinai Hospital in 1990 where he is currently the Director of Interventional Cardiology (since 1996), Director of Clinical Cardiology (2011), Dean of International Clinical Affiliations (2011), President of Mount Sinai Heart Network (2011) and is the Zena and Michael A. Wiener Professor of Medicine, Cardiology (2002).

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Residency, Medicine/Cardiology: University of Wales Cardiology, United Kingdom
Fellowship, Cardiology: Mount Sinai Hospital
Fellowship, Interventional Cardiology: Mount Sinai Hospital

Dr. Kini was newly appointed director of the Cath Lab in 2011. Dr. Annapoorna Kini 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%. In August of 2009, a New York state report named her as the safest operator among 350 other physicians. 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 like Optical Coherence Tomography and Infrared Spectroscopy. Dr. Kini also specializes in the non-coronary interventions of mitral and aortic balloon valvuloplasty, alcohol septal ablation for obstructive hypertrophic cardiomyopathy, and catheter-based aortic valve implantations. Besides being a superb interventionalist, Dr. Kini is an excellent teacher, educating both cardiology and interventional fellows on various aspects of cardiac catheterization and coronary interventional techniques. As Director, she has taken a leadership role in enhancing the research programs of the Mount Sinai catheterization laboratory. Several ongoing projects in coronary imaging are currently underway, including the YELLOW Trial and various YELLOW sub-studies. Dr. Kini is also the lead enroller for several multi-center national clinical studies, including the Triton Side Branch Stent study, Color Registry, and the Expert CTO trial. In 2011, Dr. Kini received the “Rock Star of Science” award from American Heart Association. She is the recipient of 2011 Dean's Award for Excellence in Clinical Medicine at The Mount Sinai Medical Center for unprecedented clinical skills. She has been listed as a New York Times Magazine Super Doctor 2009 until 2012.

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Residency, Internal Medicine: Brigham and Women’s Hospital
Fellowship, Cardiology: Massachusetts General Hospital
Fellowship, Interventional Cardiology: Massachusetts General Hospital

Dr. Pedro R. Moreno is a world-renowned expert in atherosclerosis, and a pioneer in the understanding of inflammation and acute coronary syndromes. His groundbreaking work with atherosclerotic neovascularization, intra-plaque hemorrhage, the role of macrophages and tissue factor in patients with acute coronary syndromes has greatly enhanced the body of knowledge in this emerging area of cardiology. These findings provided the rationale for revolutionary state-of-the-art therapies including anti-inflammatory and anti-proliferative drug-eluting stents used worldwide. His research using near-infrared spectroscopy was pivotal in the development of the now-ubiquitous LipiScan catheter. He is board certified in cardiology and interventional cardiology, and committed to teaching around the world, with professorships in multiple international organizations. Dr. Moreno works to improve cardiovascular health in the Latino community of New York, with extensive clinical work and educational media interviews. As an interventionalist, Dr. Moreno performs more than 1,000 procedures (including diagnostic and intervention) per year, with less than 1% major complications. Dr. Moreno is also a mentor for young interventional cardiologists.

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Assistant Director, Cardiac Cath Lab

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Residency, Internal Medicine: Mount Sinai Hospital
Fellowship, Cardiology: Mount Sinai Hospital
Fellowship, Interventional Cardiology: Mount Sinai Hospital

Dr. Michael C. Kim currently performs over 1,500 diagnostic catheterization procedures and over 600 percutaneous coronary interventions annually. He has quickly developed an outstanding clinical reputation within the tri-state area and boasts a superb safety record. Dr. Kim serves as both Director of the Coronary Care Unit and Director of Medical Education in the Cardiac Catheterization Laboratory at Mount Sinai Heart. As Director of the Coronary Care Unit, Dr. Kim is recognized as an expert in the management of critical care cardiology especially in the area of acute coronary syndromes, ambulatory PCI, and vascular access. He has published extensively and lectured frequently in multiple aspects of interventional cardiology.

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Fellowship, Cardiology: Ochsner Clinic Foundation
Fellowship, Interventional Cardiology: Mount Sinai Medical Center
Fellowship, Endovascular Intervention: North Central Heart Institute

Dr. Prakash Krishnan is the Director of Endovascular Intervention at the Cardiac Catheterization Laboratory of Mount Sinai Heart. He is board certified in internal medicine, cardiovascular disease, endovascular medicine and interventional cardiology. His expertise includes non-surgical treatment of coronary and peripheral vascular disease including coronary stents, carotid stents, peripheral vascular angioplasty, laser atherectomy, directional atherectomy, renal stenting and limb salvage.

Dr. Krishnan performs over 600 coronary and peripheral interventions annually. He is Director of the one-day Endovascular Symposium as part of the annual Complex Coronary Symposium held here at Mount Sinai Medical Center. A patient advocate and educator, Dr. Krishnan has a community based outreach program that serves a vast population of patients with arterial disease at offices in all five boroughs. He has been on staff at Mount Sinai Medical Center since 2004.

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Residency, Internal Medicine: Miriam Hospital, Brown University, Providence, RI
Fellowship, Cardiology: Mount Sinai Medical Center
Fellowship, Interventional Cardiology: Mount Sinai Medical Center

Dr. George Dangas performs 300 cardiovascular interventional procedures annually to treat coronary and valvular heart disease, aortic, carotid and peripheral arterial disease and hypertension. Dr. Dangas is a leading authority in the performance of nonsurgical cardiac and vascular interventions (e.g. stent, angioplasty, atherectomy) using both established and novel techniques and in the development of collaborative innovative approaches to treat complex problems across many specialties. He is currently serving as the Chair of the Interventional Scientific Council and a Trustee of the American College of Cardiology and has previously been in the board of Trustees of the Society for Cardiovascular Angiography & Interventions. He is a co-director of the annual conferences Transcatheter Cardiovascular Therapeutics and Interventional Fellows’ Courses in the USA and Europe and 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.

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Roxana Mehran, MD, FACC, FACP, FCCP, FESC, FAHA, FSCAI
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Director of Interventional Cardiovascular Research and Clinical Trials

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Residency, Internal Medicine: University of Connecticut
Fellowship, Cardiovascular Disease: Mount Sinai Medical Center
Fellowship, Interventional Cardiology: Mount Sinai Medical Center

Dr. Mehran 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, as well as 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 frequent invited speaker 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 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 Mount Sinai School of Medicine.

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Fellowship, Cardiology: Columbia-Presbyterian Medical Center

Dr. Sean Pinney is a well-known cardiologist specializing in the management of patients with advanced heart failure. Together with Dr. Anelechi Anyanwu, Dr. Pinney established Mount Sinai’s ventricular assist device program which offers a broad array of temporary and implantable devices for patients with cardiac failure. Under his leadership, the heart transplant program at Mount Sinai has increased its clinical volume and improved patient outcomes. He has been recognized by his peers and Castle Connolly as being one of New York’s best doctors. Dr. Pinney is an active clinical researcher who has led both NIH and industry-sponsored trials in the areas of cardiac transplantation and mechanical circulatory support. He serves on the American College of Cardiology Heart Failure and Transplant committee, the United Network for Organ Sharing (UNOS) MPSC committee and the medical advisory board for the New York Organ Donor Network.

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Dr. Barry Love is director of the congenital cardiac catheterization laboratory at Mount Sinai Heart. Dr. Love holds a joint appointment in both the department of Pediatrics and the Department of Medicine and is one of only a few physicians who perform interventional procedures on patients with congenital heart disease from infancy through adulthood. He has been a pioneer in extending many of the techniques used in the treatment of congenital heart disease, to acquired heart lesions in adults such as perivalvular leaks and post-infarction ventricular septal defects. He has been recognized by Castle Connolly as one of America's Top Doctors for 2009-2012 and is listed as a New York Times Magazine Super Doctor from 2008 until 2012. Dr. Love's research interest is in new device technologies and he is a principal investigator for several device trials in congenital heart disease.

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Fellowship Cardiology: Tulane University School of Medicine
Fellowship, Interventional Cardiology: Ochsner Clinic Foundation
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Clinical Interests: Pulmonary Hypertension, Advanced Heart Failure & Mechanical Support, Cardiac Transplantation
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Atul M. Limaye, MD, MRCP
Assistant Professor of Medicine, Cardiology
Education and Training
MBBS: MAMC, University of Delhi, India
Residency: Bronx Lebanon Hospital Center, NY
Fellowship, Non-invasive Cardiology: Brigham & Women's Hospital, Boston
Fellowship, Cardiology: Montefiore Medical Center, NY
Fellowship, Interventional Cardiology: Mount Sinai Medical Center, NY
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PhD: Victor Chang Cardiac Research Institute through University of New South Wales, Australia
Residency, 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: Mount Sinai Hospital
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Fellowship, Interventional Cardiology: Mount Sinai Hospital
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MS: Columbia University, New York, NY
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Fellowship, Cardiology: Mount Sinai School of Medicine, New York, NY
Fellowship, Interventional Cardiology: Mount Sinai Hospital, New York, NY
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Fellowship, Interventional Cardiology: Mount Sinai Hospital
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Education and Training
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Residency, Internal Medicine: University of Pittsburgh
Fellowship, Cardiology: North Shore University Hospital at Manhasset
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Clinical Interests: Clinical Cardiology, Fellows’ Education, Cardiac Catheterization
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MD: Mount Sinai School of Medicine  
Residency, Internal Medicine: Mount Sinai Hospital  
Fellowship, Cardiology: Mount Sinai Hospital  
Fellowship, Interventional Cardiology: Mount Sinai Hospital  
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Associate Professor Medicine, Cardiology  
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Residency, Internal Medicine: Mount Sinai Hospital  
Fellowship, Cardiology: Mount Sinai Medical Center  
Fellowship, Clinical Heart Failure and Molecular Cardiology: University of Toronto  
**Clinical Interests:** Clinical Cardiology, Biostatistics, Interventional Cardiology  
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Anthony T. Shih, MD  
Clinical Instructor Medicine, Cardiology  
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Residency, Internal Medicine: Hospital of the University of Pennsylvania  
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Fellowship, Cardiac Catheterization, Nuclear Cardiology: Lenox Hill Hospital
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Assistant Clinical Professor Medicine, Cardiology
Education and Training
MD: Albert Einstein College of Medicine
Residency, Internal Medicine: Bronx Municipal Hospital Center
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**Choudhury M. Hasan, MD**  
Assistant Clinical Professor Medicine, Cardiology  
**Education and Training**  
MBBS: Dhaka Medical College, Dhaka, Bangladesh  
Residency, Internal Medicine: The Brooklyn Hospital Center  
Fellowship, Cardiology: The Brooklyn Hospital Center  
Fellowship, Interventional Cardiology: Deborah Heart and Lung Center  
**Clinical Interests:** Cardiac Catheterization, Coronary Interventions, Echocardiography  
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**Claude Simon, MD**  
Assistant Clinical Professor Medicine, Cardiology  
**Education and Training**  
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Residency, Internal Medicine: Yale, New Haven, Greenwich Hospital, Connecticut  
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**Timothy G. Jayasundera, MD**  
Clinical Instructor, Medicine, Cardiology  
**Education and Training**  
MD: Ross University School of Medicine  
Residency: Georgetown University Medical Center  
Interventional Cardiology Fellowship: The Mount Sinai Medical Center  
Cardiology Fellowship: Drexel Hahnemann University Hospital; Philadelphia, Pennsylvania  
**Clinical Interests:** Interventional Cardiology, Aspirin and Clopidogrel Resistance, Acute Coronary Syndromes, Peripheral Arterial Disease (PAD)  
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Email: jayasunderamdpc@yahoo.com

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**Niranjan K. Mittal, MD**  
Clinical Instructor Medicine, Cardiology  
**Education and Training**  
MBBS: Government Medical College, Patiala, India  
Residency: Internal Medicine, Jamaica Hospital, New York  
Fellowship, Cardiology: The Brooklyn Hospital  
Fellowship, Interventional Cardiology: The Mount Sinai Medical Center  
**Clinical Interests:** Cardiac Imaging, Interventional Cardiology  
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Lynne Glasser, MD  
**Assistant Professor Medicine, Cardiology**  
**Director Interventional In-Patient Service**  
**Education and Training**  
MD: SUNY Health Science Center  
Residency, Internal Medicine: New York University Medical Center  
Fellowship, Cardiology: Manhattan Veterans Administration Medical Center  

Since joining Mount Sinai Medical Center in November 2008, Dr. Glasser is playing an important role in the treatment and management of interventional patients, before and after the procedure.  
**Clinical Interests:** Clinical Cardiology, Preventive Cardiology  
**Phone:** 212-241-4521  
**E-mail:** lynne.glasser@mountsinai.org

Rosario Marasigan, RN  
**Clinical Nurse Manager**  
**Education and Training**  
BS: Nursing: Philippine Women's University  

Rosario Marasigan is the clinical nurse manager since 2006. In this role she efficiently & effectively manages a unit with complex staff of more than 150 health professionals. Rosario has been an excellent clinical & charge nurse for 16 years prior to being the manager. Being a nursing instructor in the past makes her a great teacher at the bedside & a role model to our new nurses in the Cath Lab. She is a certified critical care nurse and an active member of AACN since 1990.  
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**E-mail:** rosario.marasigan@mountsinai.org

Gregory Gojkovich  
**Operations Manager**  
**Education and Training**  
AA Degree, Moorpark College, California.  

Greg Gojkovich joined the Mount Sinai cath lab in January 1987. In 1992, he accepted a cath lab operational manager position at Beth Israel Medical Center, New York, NY. He returned to Mount Sinai in 2001, where he is currently the Operations Manager of Mount Sinai Heart.  
**Phone:** 212-241-1548  
**E-mail:** gregory.gojkovich@mssm.edu
Nurse Practitioner Team
Mount Sinai’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.

Antonietta Tolentino Gloria Manzanilla Rheoneil Lascano Surekha Patel Haydee Garcia
Melissa Mattimore Leticia Jakasal Suzette Chan Tanya Sullivan Tia Coleman
Kevin Williams Jennifer del Campo Supawadee Pitakmongkolkul Vivian Lau

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.

Amit Sharma, MD Georges Abourjaili, MD Gauntam Bhimidi Reddy, MD John O’Dea, MD
Bakhtiar Ali, MD Shyam Poludasu, MD Ravilla Mahidar MD Ziad Ali, MD
Interventional Research Team
(Left to Right) Michael Fusilero, Kristin Falciglia, Kameswari Vallabhajosyula, Eyal Levy, Arthur Tarricone, Theresa Franklin-Bond (Manager), Adam Asif, Laura Ramirez, EJ Fernandez, Miguel Vasquez

Interventional Database Team
(Left to Right) Roja Thapi, Denise Dwyer, Swathi Roy, Birju Narechania, Delenia Gulle, Swapna Sayeneni

A Dedicated Team
The total number of Cath Lab staff including nurses, technicians and support staff has grown to over 165 dedicated employees. Each member of the cath lab staff has a strong work ethic and takes pride in their contribution to the goal of the department – delivery of efficient and safe care to patients in need.

Supporting Staff
(Top Row) Debra Bradley, Shulandia Avila, Merlyn Blackwood, Stacyann Reid, Era Zuberko
(Bottom Row) Pearl Tongson, Jackie Nordstrom, Maria Directo
Mount Sinai of Queens, Astoria

Lutheran Medical Center, Brooklyn

St. John’s Hospital, Yonkers

Good Samaritan Hospital, Suffern

Cardiology Unlimited, Eliscer Guzman, MD, P.C.
Broadway Cardiopulmonary, P.C.
Astoria Cardiology, P.C.
Hemant Patel, MD, P.C.
Levit Medical Center, P.C., SSL Quality Care Diagnostic and Treatment Center, Inc.
Long Island Heart Associates, Steven Shayani, MD, & Associates
Family Health Cardiac Center, Niranjan Mittal, MD
Traube, Marush and Plawes, MD, P.C.
Park Avenue Family Practice, L.L.C, James Sayegh, MD
Riverside Medical Group, Sudhakar Mettu, MD & Associates
Manhattan Medical Group, Shuja Qadir, MD
Medicine from the Heart, P.C.; Gary Spektor, MD, P.C.
Mount Sinai of Staten Island, Seshadri Das, MD
Clinica Modelo, Washington Heights, P.C.
Westchester Family Practice, P.C.; Iyad Annabi, MD
Westchester Health Associates, George Berk, MD & Associates
Midland Avenue Family Practice, P.C., Steven Francescone, MD
Manuel Velasquez, MD, P.C.
Tracy Townes, MD, Chaula Patel, MD, P.C.

Arshad Anwar, MD, P.C.
Cardiology P.C.; Saeed Siddiqui, MD
Viera Henteck, MD, P.C.
We Care Health & Medical Services, P.C., Carlos Diggs, MD
Heights Medical Care, P.C;
Larry Neuman, MD
DOC Medical Office of Yonkers & Bronx; Rajeev Sindhwani, MD
Hamid and Aslam Medical Group, Inc.
JAMA, P.C.; Javed & Daniel Yadegar, MD
Bronxville Internal Medicine, P.C.
Mazan Rabadi, MD
Prime Care Medical Group, Jamaica, P.C.
Prime Care Medical of Brighton, P.C, Iffat Sadique, MD
Satyavathi Sharma, MD, P.C.
Qazi Kamal Haider, MD, P.C.
Gondal Medical Care, P.C., Imtiaz Ahmad, MD
Multi Medical Care, P.C., Ferdausi Hassan, MD
Knickerbocker Medical Care, P.C., Syed Shahid Hassan, MD
Northern Heart Specialists, P.C.
Seventh Avenue Medical, P.C, Michael Jones, MD
Panagiotis Pagonis, MD, P.C.
Juhno Lee, MD, P.C.
786 Medical P.C., Rafiq Chaudhry, MD

A great deal of Mount Sinai Cath Lab’s success comes from strong relationships with our regional colleagues. We would like to thank these partners for their continued contributions.
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CORONARY SYMPOSIUM DIRECTORS
Samin K. Sharma, MD, FSCAI
Annapoorna S. Kini, MD, MRCP

CORONARY SYMPOSIUM CO-DIRECTORS
Pedro Moreno, MD
Michael Kim, MD, FSCAI
George Dangas, MD, FSCAI
Roxana Mehran, MD, FSCAI
Robert Pyo, MD

VASCULAR SYMPOSIUM DIRECTOR
Prakash Krishnan, MD

VASCULAR SYMPOSIUM CO-DIRECTORS
J. Michael Bacharach, MD, FSCAI
Peter Faries, MD
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Purpose
These live seminars will highlight in-depth procedural techniques for managing complex coronary cases. They will be streamed in real time over the Internet, and viewers can participate in our online didactic discussion.

Learning Objectives
• Discuss the rationale for choice of percutaneous coronary intervention
• Discuss choices of antiplatelet therapy
• Demonstrate the use of plaque modification, especially Rotablator
• Demonstrate the application of large, randomized drug-eluting stent clinical trial results within an interventional clinical practice

Target Audience
Cardiologists, interventional cardiologists, fellows, cardiovascular technicians, and cath lab nurses
Please visit www.wwwcccclivecases.org

2012 Web Conference Schedule
8:00 TO 9:00 AM
June 19
July 17
August 21
September 18
October 16
November 20
December 18

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<td>Vascular Laboratory</td>
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At the Cardiac Catheterization Lab at Mount Sinai Heart, our mission is to provide the best possible outcome for every interventional patient we treat.