CARDIAC CATH LAB

2013 CLINICAL OUTCOMES REPORT



PATIENT-CENTERED CARDIAC EXCELLENCE



A Message From Dr. Sharma & Dr.Kini



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Dear Colleague:

We from the Cardiac Catheterization Laboratory at Mount Sinai Heart take great pride in presenting our patient-centered 2012 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. In this issue, we have highlighted our performance metrics and compared them to 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 the management of moderate to severe CAD, while coronary artery bypass surgery has been shown to improve long-term survival of patients with extensive CAD. The landmark FREEDOM Trial continually showed CABG to be superior to DES PCI over the long term in regard to mortality. Stable interventional growth with declining complications despite the increasing complexity of cases has been made possible by teamwork and dedication to 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 smiles on their faces.

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 2013 is to rise to eminence from excellence by innovation and well-organized comprehensive care in the field of interventional cardiology.

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Mount Sinai Hospital Cardiac Cath Lab: Clinical Outcomes 2013

Welcome



Kenneth L. Davis, MD President and Chief Executive Officer The Mount Sinai Medical Center



Dennis S. Charney, MD Anne and Joel Ehrenkranz Dean Icahn School of Medicine at Mount Sinai

Dear Colleagues:

It is our honor to share with you the fifth 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* (2008-2010), 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



Valentin Fuster, MD, PhD, MACC

Physician-in-Chief, The Mount Sinai Medical Center

Director, Mount Sinai Heart

Director, Zena and Michael A. Wiener Cardiovascular Institute and of the Marie-Josée and Henry R. Kravis Center for Cardiovascular Health

Richard Gorlin, MD Heart Research Foundation Professor of Cardiology The field of cardiovascular medicine is exploding. Every day, the instruments we wield are becoming more specialized, and our diagnostic approaches are becoming more sophisticated, all for the benefit of our patients.

Now only in its seventh year, Mount Sinai Heart is recognized around the world as a leading institution, and the Cardiac Catheterization Laboratory, led by Samin K. Sharma, MD, has played an important part in its rise to prominence. Dr. Sharma is a physician of exacting clinical standards, and he is also a man who inspires by example. This has helped him put together a loyal team of interventionalists and support staff whose standards are just as high. His patients simply adore him, as you will see from the testimonials in the following pages.

Patients come to the Cath Lab from every borough in the city and from the entire tristate area. They arrive at every hour of the day and night. They may have an elective procedure scheduled, or they may be in the throes of a myocardial infarction. Whether the situation is routine or a matter of life or death, every member of the team is well prepared and stands ready to deliver care of uncompromising quality.

Research might be called the engine of advancement in medicine. Mount Sinai is often a participating site in a clinical trial, and our interventionalists are well versed in the current literature and guided by trial outcomes, which offer new hope for certain patient populations. Among the many discussed in this report are studies on resistant hypertension; treatment of coronary bifurcation lesions; patients with renal insufficiency undergoing catheterization; adherence to dual antiplatelet therapy (DAPT); criteria for revascularization choices in patients with threevessel coronary disease; intravascular brachytherapy; transradial versus transfemoral access for PCI; and the very promising transcatheter aortic valve replacement (TAVR).

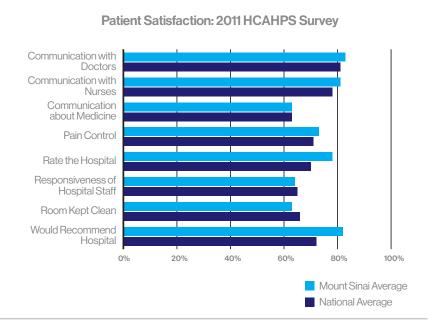
On the subject of TAVR, one year ago, we reported that Mount Sinai was a participant in the CoreValve U.S. Pivotal Trial, and that the first procedure, to replace a diseased aortic valve percutaneously, was performed right here, by Dr. Sharma and David H. Adams, MD. At the end of 2012, we had performed 100 transcatheter aortic valve replacements, and we can report another "first." Daquain Jenkins was the first patient in the tristate area to leave the hospital with the SynCardia Total Artificial Heart pumping in his chest; he was discharged on October 25, 2012, but he will return to Mount Sinai as soon as a donor native heart becomes available.

Again this year we offer "testimonials" from grateful patients, but we have chosen to have them photographed in their homes, or in the park, or at the beach, or walking to work. The settings are appropriate, because we strive, whenever possible, to make our patients well and send them home to resume their regular lives. That is at the heart of what we do.

The Cardiac Catheterization Lab

An Overview of Services and Outcomes

Thomas Edison once said, "The three great essentials to achieve anything worthwhile are: first, hard work, second, stick-to-it-iveness, and third, common sense." These three essentials, along with teamwork are the fundamentals of the success of our Cath Lab.



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 10th in 2012 (U.S. News & World Report 2012).

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 rooms (hybrid cath labs) are equipped to perform transcatheter aortic valve replacement (TAVR). All cath rooms are equipped with intravascular ultrasound (IVUS), and five rooms have fractional flow reserve (FFR) capability. Our Cath Lab has incorporated other imaging modalities, such as optical coherence tomography (OCT) and near-infrared spectroscopy (NIRS).

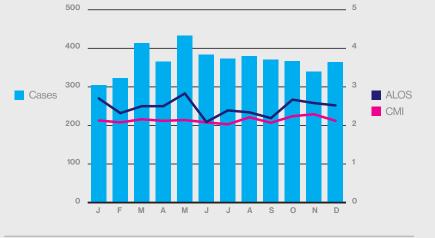
Efficiently managing the growing volume and complexity of invasive cases is demanding on our physical infrastructure and our Cath Lab staff. The numbers of both medical and nonmedical staff have shown tremendous growth, to over 185, with the ultimate goal of delivering safe, appropriate and excellent care.

Presently there are five full-time senior attendings, 12 full-time affiliate attendings, 11 voluntary interventional attendings, four voluntary cath attendings, three CHF/transplant attendings, one pediatric cath

Inpatient Volume, CMI, and ALOS for 2012

attending, eight interventional fellows and 15 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 42 percent of our elective interventional patients are safely discharged on the day of the procedure (Ambulatory PCI) following an established ambulatory discharge protocol. Others with more complex interventions, comorbid conditions and higher acuity are admitted for observation; the majority are discharged home the next day. The chart on this page depicts our inpatient volume, average length of stay (ALOS, which is usually 0.85 of expected LOS), and case mix index (CMI, a measure of a patient's medical acuity based on associated medical conditions).

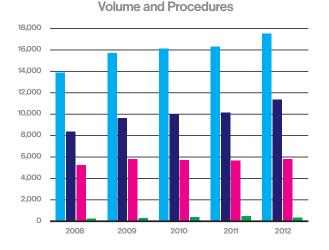
In this competitive environment, only the best can flourish, and that is exactly what our Cath Lab has done, delivering the best and the safest invasive/interventional care to cardiac patients, with innovation and procedural excellence. On the following pages are some of the important attributes of the Cardiac Cath Lab.

Comparative Quality Parameters of Interventional Procedures

Growth and Trends in Cath Lab Volume and Procedures

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 a significant increase in endovascular and valvular interventions.



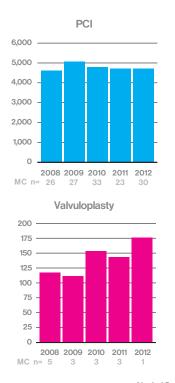


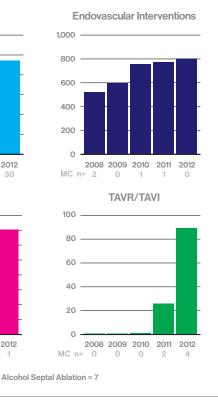
Growth and Trends in Cardiac Cath Lab

With over 5,000 interventions each year for the last four years, our Cath Lab is the leader in interventions in the U.S.



Interventional Volume and Major Complications (MC)





Total percutaneous interventions encompass percutaneous coronary interventions (PCI, for coronary artery disease); endovascular interventions (for diseased limb, cerebral, or renal arteries); valvuloplasties (for stenosed aortic or mitral valves); transcatheter aortic valve replacement/implantation (TAVR/TAVI, for stenosed aortic valves); alcohol septal ablation (for hypertrophic obstructive cardiomyopathy, HOCM); and interventions for other structural heart diseases, such as ASD and PFO closure. In 2012 we performed a record 5,806 interventions: 4,729 PCI, 805 endovascular interventions, 149 balloon aortic valvuloplasties, 27 balloon mitral valvuloplasties, 89 TAVR and seven alcohol septal ablations. In mid-2012, we started performing intravascular brachytherapy (IVBT) for recurrent restenosis (more than twice) after drug-eluting stents. Carotid stenting is now routinely being performed by our interventionalists, in conjunction with vascular surgeons; 40 cases were successfully performed in 2012 without any major complications. The majority of PCIs (95 percent) are done using stents (DES in 94 percent; BMS in 6 percent) with adjunct 10 percent rotational atherectomy and 2 percent thrombectomy/distal protection device and the remaining 5 percent percutaneous transluminal coronary angioplasty (PCTA) only.

Some of the growth can be attributed to our 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 2012, 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.

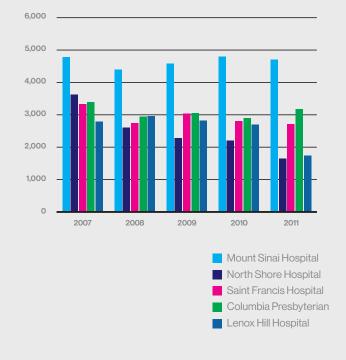
NYS DOH-Reported PCI Volumes in Comparison to Other NY Centers

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 more than 1,500 interventions over any other center since 2007, according to New York 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 2012; combined major complications of death, large MI, urgent CABG, and CVA cases under 0.6 percent.

This remarkable growth with low complications has been achieved despite the high complexity and co-morbid medical conditions of patients being treated in the Cath Lab. Reports of riskadjusted PCI mortality over the last 15 years by the NYS DOH have consistently placed the Mount Sinai Heart Cath Lab among the lowest for in-hospital and 30-day risk-adjusted mortality. The recent NYS DOH report of 30day risk-adjusted mortality for year 2010 has shown an incidence of 0.64 percent for all cases, 0.41 percent for elective cases and 2.55 percent for emergency PCI cases; the lowest in the state and about 30 percent lower than the statewide average. We are one of two centers to receive a double star (**) notation of superior



NYS DOH-Reported PCI Volumes

0.8% 0.6% 0.4% 0.2% 0% In-Hospital Urgent Q-Wave/ Major Death CABG Large MI Complications (Death, uCABG, MLCVA) 2008 (n=4,594) 2009 (n=5,078) (n=4,799) 2011 (n=4,707) 2012 (n=4,729)

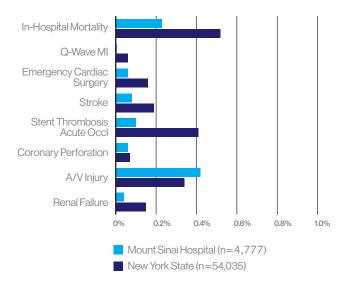
Temporal Trends in Complications of PCI at MSH

PCI Statistics for 2008-2010	# Cases	All Cases	Non-Emergency Cases	Emergency Cases
1. Mount Sinai Hospital	14,414	0.64**	0.41**	2.55
2. Saint Francis Hospital	9,045	0.61**	0.35**	2.74
3. Columbia Presbyterian Hospital	8,750	0.87	0.59	2.36
4. Lenox Hill Hospital	8,504	0.81	0.47	3.24
5. Saint Joseph Hospital	6,510	0.83	0.58	2.57
6. North Shore Hospital	6,112	0.70	0.56	1.72*
7. LIJ Medical Center	5,896	0.63	0.36	2.45
3. Rochester General Hospital	5,801	1.29*	0.77*	4.33
9. Stony Brook Hospital	5,335	0.98	0.58	3.48
0. Beth Israel Medical Center	5,073	0.65	0.30**	3.70
NYS Total	162,918	0.90	0.55	3.17

NYS-DOH Report of PCI 2008-2010

**Risk Adjusted Mortality Rate (RAMR) significantly lower than statewide rate *RAMR significantly higher than statewide rate

NYS-Reported Major Complications Following PCI 2010





	MSH	NYS
	(n=4,777)	(n=54,035)
Ethnicity, Hispanic/South Asian (%)	26.46/20.47	11.59/8.27
Primary Payer; Medicaid (%)	40.03	19.28
Age >85 yrs (%)	3.64	4.24
Peripheral vascular disease (%)	15.97	8.77
DM on medication (%)	45.64	34.86
Renal failure on dialysis (%)	3.79	2.40
Prior CVA (%)	11.53	8.39
Left-Main disease (%)	5.82	3.91
Rotational atherectomy (%)	9.06	2.12
DES use (%)	71.68	50.77

Excellent outcomes are achieved despite a high volume of challenging complex cases with high baseline risk factors.

safety in at least two PCI categories (all cases and, nonemergency cases; receiving the double star for RAMR outcomes has been a constant over the last 15 years of NYS DOH PCI reporting). Receiving the double star every year in two PCI categories is truly unprecedented for any PCI center in the state.

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 2009 report, Dr. Sharma was awarded the double-star designation by New York State denoting significantly lower 30-day risk-adjusted mortality among approximately 600 interventionalists practicing in the state. In the 2010 report, Dr. Pedro Moreno, for the first time received the double-star designation. 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 at left, confirms significantly better outcomes in most of the commonly reported procedural complications despite higher adverse factors of PCI patients when compared to New York State.

Comparison of Mount Sinai Hospital Interventional Outcomes with Others

The following graphs show the superior outcomes of PCI patients at Mount Sinai Hospital in comparison to NY State, ACC-NCDR and Cleveland Clinic Hospital.

Other Quality Interventional Parameters of Mount Sinai Hospital

Appropriateness of PCI for Stable CAD

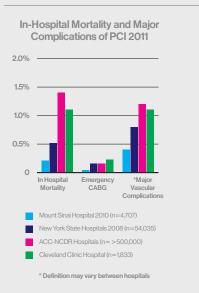
Currently appropriateness of PCI has come under strong scrutiny. Cases that are inappropriate based on the published guidelines are not only risky to the patient because the intervention is not indicated but also at risk of being denied payment. At Mount Sinai we established the evidencedbased system protocol of proper evaluation of CAD patients before scheduling for catheterization and possible intervention and then rigorous application of the appropriate use criteria (AUC) of the American College of Cardiology; this has yielded one of the lowest rates of inappropriate PCI for stable CAD in the nation.

Primary PCI < 90 Minutes

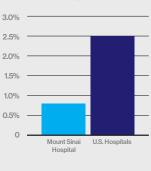
PCI performed in less than 90 minutes is an important quality CMS parameter and is publicly reported for all hospitals. The proportion of STEMI patients at Mount Sinai Hospital undergoing PCI in less than 90 minutes was 100 percent in 2012.

In-Hospital Mortality of STEMI Patients

According to the ACC/NCDR Report, riskadjusted mortality of STEMI patients at Mount Sinai Heart is less than 50 percent of that of other comparable U.S. hospitals.



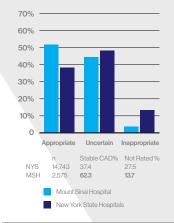
In-Hospital Complications of PCI* 2012



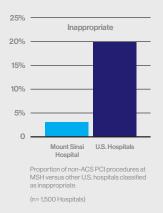
*Death, emergency CABG, stroke or TVR, at Mount Sinai compared to USA ACC-NCDR (n=1,500 Hospitals)

Appropriateness of PCI for Stable CAD

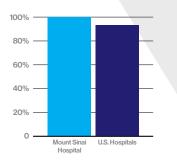
Appropriateness of Revascularization by PCI: NYS vs MSH for Stable CAD in 2010



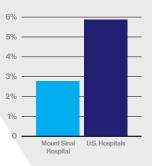
Appropriateness of PCI AUC Metrics at MSH compared to U.S.: ACC-NCDR Q3-4 2012



Proportions of STEMI underwent PCI <90 Minutes



In-Hospital Mortality for STEMI (Risk-Adjusted)



Innovations Samin K. Sharma, MD, FSCAI, FACC



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 Updated Criteria for Revascularization Choices in Complex Coronary Artery Disease, Incorporating Five-Year SYNTAX and FREEDOM Trial Results

The SYNTAX (SYNergy Between Percutaneous Coronary Intervention with TAXus and Cardiac Surgery) Trial, which was 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 percutaneous coronary intervention (PCI) and open heart surgery (CABG). This measurement is known as a SYNTAX score.

At Mount Sinai Heart, we have been incorporating SYNTAX scores in the stratification of patients with advanced coronary artery disease (CAD) for choice of revascularization modality (PCI vs. CABG). Late in 2012, five-year follow-up data from the SYNTAX Trial revealed that patients in the CABG arm, including those whose SYNTAX scores were in the

"I accept that I will always have heart trouble, and I hope that I will always have Mount Sinai and Dr. Sharma."

Patient:	Sunil Kastiya 52-year-old male
Diagnosis:	Positive stress test; coronary atherosclerosis of native vessel
Treatment:	Successful intervention of LCx; implantation of drug-eluting stent

"I have a family history of heart disease, and in 1992, when I was only 32, I had a severe heart attack. I was treated at a local hospital, but my father and Dr. Sharma are members of the same religious community, and other members suggested that he talk to Dr. Sharma about my case.

"So my father, who was very worried about me, brought Dr. Sharma my reports from the first hospital, and Dr. Sharma said he would see me in his office. I remember that he came over from the Cath Lab still wearing his scrubs, obviously a very busy doctor, but he was so nice and so sympathetic that already I felt 50 percent cured.

"They did all the tests, and then I was scheduled for angiography — my first procedure. I was so nervous and afraid that I actually fainted before they took me into the Cath Lab, but I survived, thanks to Dr. Sharma. He is a wonderful doctor as well as a wonderful man.

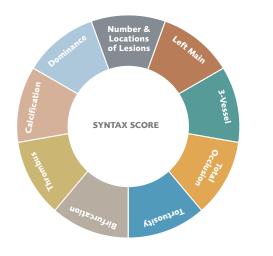
"Since then, I have had further procedures, most recently angioplasty with implantation of a stent in 2010, and they have all been performed by Dr. Sharma. I accept that I will always have heart trouble, and I hope that I will always have Mount Sinai and Dr. Sharma."



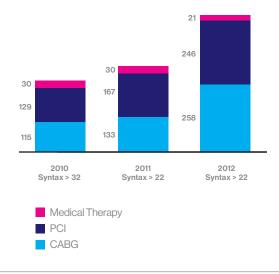
intermediate range (23 to 32), after five years were noted to have a significantly lower endpoint of death, myocardial infarction, stroke or revascularization when compared to patients undergoing PCI with implantation of drug-eluting stents (DES). This observation held true for both diabetic and non-diabetic patients. In response, we lowered the bar for CABG and began preferentially to refer patients whose scores were in the intermediate range, and who were not at high risk for undergoing cardiac surgery. This has increased CABG rates in advanced CAD at many hospitals, including Mount Sinai.

The FREEDOM (Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease) Trial was a five-year, multicenter superiority trial in which 1,900 patients with diabetes and multivessel CAD, with a mean age of 63, were randomly assigned to CABG or PCI with a drug-eluting stent at 140 centers. Five-year data was presented at the American Heart Association Scientific Sessions in November 2012, with simultaneous publication in the *New England Journal of Medicine*.

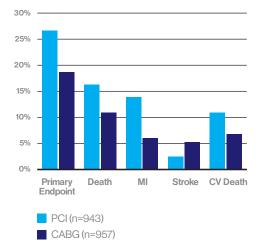
The FREEDOM data showed that the primary outcome — a composite of all-cause mortality, nonfatal myocardial infarction (MI) or nonfatal stroke — occurred more frequently in those who underwent PCI versus CABG. Five-year rates were 26.6 percent in the PCI group compared with 18.7 percent in the CABG group. MI rate and all-cause mortality rate also significantly favored CABG over PCI (6 percent vs. 13.9 percent, 10.9 percent vs. 16.3 percent, respectively). Only stroke occurred more frequently in the CABG group (12.4 percent vs. 5.2 percent in the PCI group). These outcomes were not affected by SYNTAX scores. "In patients with diabetes and multivessel coronary disease, CABG was of significant benefit compared with PCI," concluded Valentin Fuster, MD, lead researcher and director of Mount Sinai Heart, who presented the data, "CABG surgery is the preferred method of revascularization for patients with diabetes and multivessel disease."



Revascularization Choices For High Syntax Score Patients at Mount Sinai Hospital







Therefore, diabetic patients with three-vessel CAD, irrespective of their SYNTAX scores, as well as nondiabetic patients with SYNTAX scores equal to or above 22, must discuss with the heart team (surgeon, interventionalist, cardiologist or patient's referring physician), *in a setting other than the procedure room*, the most appropriate revascularization choice, with CABG being advised categorically. The only exception to this rule is the case where the referring physician, who is not an 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 or her.

It is important to note that when confronted with the choice between bypass surgery and PCI, it is the natural human tendency to select the latter. To overcome this predisposition, it is essential that these patients be removed from the Cath Lab to another area (e.g., the holding area or the telemetry unit), where all the data, particularly the survival advantage of CABG, can be presented to them and they can weigh the decision as calmly and unemotionally as possible. If these patients continue to opt for PCI, a separate consultation with a cardiac surgeon is required; only after this consultation the patient's firm refusal for CABG should be entertained and PCI can be done.

Diabetic patients with three-vessel CAD or nondiabetic patients with SYNTAX scores equal to or above 23 might be excluded from CT surgery consultations if the following situations or comorbidities are present:

- Acute MI (STEMI or non-STEMI)
- Age above 85
- Prior CVA or recent TIA
- Severe COPD (FEV1 below 50 percent predicted)
 and on chronic bronchodilator therapy
- Body mass index (BMI) above 50
- LV ejection fraction below 30 percent
- Participation in IRB-approved PCI trial
- · Limited life expectancy of less than one to two years

"I had never heard of brachytherapy, but after the treatment, I felt much better... I'm very grateful to Dr. Sharma for his excellent work."

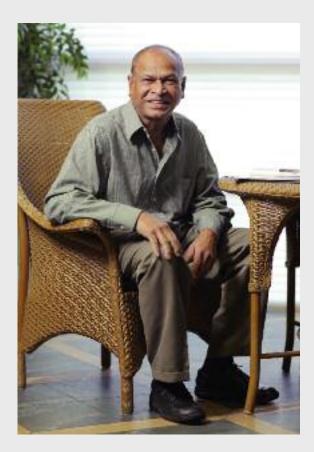
Patient:	Madhan Sakhichand, 65-year-old male
Diagnosis:	In-stent restenosis of RCA (proximal), RCA (mid)
Treatment:	Intervention with intravascular brachytherapy of RCA proximal and mid

"In 1997, on Thanksgiving, I was playing cricket in the Bahamas when I suffered a heart attack. My wife and I flew back to New York for treatment, and I received my first stent in an area hospital. In 2001, I began having heart problems again, and between 2001 and 2005, I received 13 stents. I wonder if that is some kind of record!

"I felt pretty well for a few years, and then in 2012 I began having problems again. In November, I saw a cardiologist at another area hospital, and he told me, 'Given the seriousness of your condition, only Dr. Sharma at Mount Sinai can help you.'

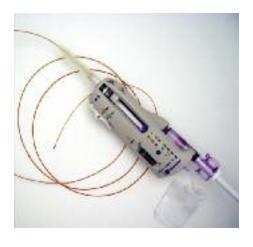
"Dr. Sharma explained that I had something called in-stent restenosis, which means that my arteries were closing again because of scar tissue in my stents. The treatment he gave me, called brachytherapy, cleared the stents with radiation.

"I had never heard of brachytherapy, but after the treatment I felt much better, although I think my days playing cricket are over. I'm very grateful to Dr. Sharma for his excellent work."

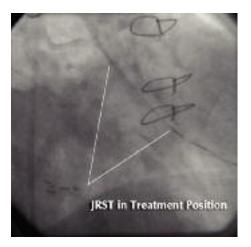


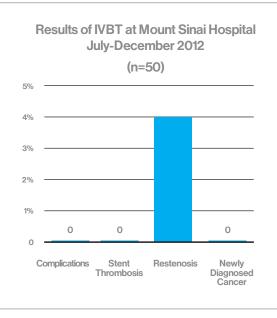


Novoste[™] Beta-Cath[™]3.5F System



Brachytherapy Catheter in Treatment Position





Reintroduction of Intravascular Brachytherapy (IVBT) for Recurrent In-Stent Restenosis

Everything old is new again, the saying goes, and that is true of intravascular brachytherapy (IVBT) for in-stent restenosis, a treatment offered here at Mount Sinai in the past that is undergoing a revival today.

From February 2000 to April 2004, 373 patients at Mount Sinai with in-stent restenosis underwent cutting balloon percutaneous transluminal coronary angioplasty (PTCA) or rotational atherectomy followed by the delivery of beta radiation to the site of the restenosis, using the Novoste[™] Beta-Cath[™] system. While early results with these patients were favorable, the therapy fell into disuse with the advent of the drug-eluting stent (DES).

Drug-eluting stents proved superior to bare metal stents (BMS) in treating restenosis, but despite their introduction, the chances of hyperplasia (scar tissue formation) in the stented area are anywhere from 1 to 10 percent, based on the complexity of the lesion. The usual treatment for these patients is enlarging the lumen with balloon angioplasty, cutting balloon atherotomy, Rotablator or restenting. Despite multiple restenting treatments, a small number of patients continue to develop reblockages, largely because of aggressive intimal hyperplasia.

Therefore, the old, established technique of intravascular brachytherapy (IVBT), using the Beta-Cath system, is being revived here at Mount Sinai for patients who have at least two layers of drug-eluting stents and have come back with reblockages for the third or fourth time. It is done in conjunction with a radiation oncologist and a radiation physicist in the Cath Lab. The system consists of a closedend delivery catheter, a source train containing radioactive seeds, and a transfer device used to store and deliver the source train. The transfer device delivers the radioactive seeds to the artery to administer radiation, and after an appropriate length of time (less than five minutes) the seeds are returned to the transfer device. The system works by inhibiting smooth-muscle-cell proliferation within the stent that causes the restenosis.

Since July of 2012, about 50 patients with in-stent restenosis have been treated at Mount Sinai using intravascular brachytherapy; there have been no complications, and based on preliminary data there have been two reblockages. IVBT appears to have reclaimed its place in the interventional cardiologist's arsenal of weapons.

"To me he is a star of the first magnitude one of the brightest stars in the sky."

Patient:	Philip Borsuk, 84-year-old male
Diagnosis:	Acute on chronic diastolic heart failure, aortic valve disease
Treatment:	Implantation of Edwards SAPIEN [™] valve

"About 25 years ago, in Los Angeles, I had a heart attack followed by triple bypass. I exercised and watched what I ate and felt quite well for a long time, although a couple of years ago my LA cardiologist heard a murmur, did an angiogram, and told me my aortic valve was calcifying. He said we would watch it but it might not get any worse.

"Well, it did get worse, and I began to get symptoms — tightness in the chest, dizziness — which was when I was referred to Dr. Sharma in New York, where my wife and I live part of the year. In the fall of 2012, he performed catheterization, and afterward he told me, with a big, confident smile, 'Your heart is strong, your arteries are clean, and we can take care of your aortic valve.'

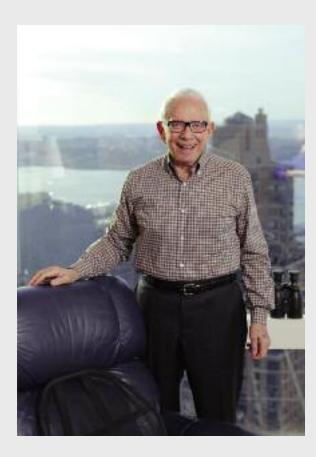
"On December 13, 2012, Dr. Sharma replaced my native valve with an Edwards SAPIEN[™] valve in a percutaneous procedure. Everything went smoothly. The next day I was up and walking briskly in the CCU, and the day after that I went home.

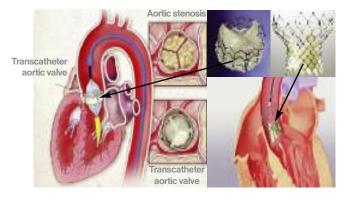
"I've been fortunate to have excellent cardiac care when I needed it. My triple bypass was performed by a student of renowned cardiac surgeon Michael DeBakey, MD and Dr. Sharma is a cardiologist of that high caliber. When I met him, I said, 'Dr. Sharma, I have heard so many wonderful things about you, I expected you to be 17 feet tall.' To me he is a star of the first magnitude — one of the brightest stars in the sky."

Update on Transcatheter Aortic Valve Replacement/Implantation

Today it can be said with confidence that the era of transcatheter aortic valve replacement/implantation (TAVR/TAVI) has arrived.

In the May 3, 2012, issue of the New England Journal of Medicine, two articles gave support to this statement. In the first article, it was noted that the PARTNER A (Placement of Aortic Transcatheter Valves) Trial of the Edwards Lifesciences SAPIEN[™] transcatheter heart valve had shown that among high-risk patients with aortic stenosis (Cohort A; n = 699) who were randomly assigned to transcatheter aortic valve replacement (TAVR) or surgical replacement (SAVR), the one-year survival rates were similar. According to the article, two-year follow-up of these patients supports TAVR as an alternative to surgery in high-risk patients. The two





Percutaneous Heart Valves in USA

Edwards SAPIEN®Valve

CoreValve®

Transcatheter Aortic Valves

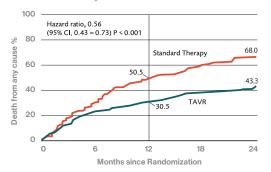
	Edwards SAPIEN Valve	Medtronic CoreValve
Expansion	Balloon-expandable	Self-expandable
Frame	Stainless steel	Nitinol
Valve material	Bovine	Porcine
Sheath size	21-24 Fr	18 Fr
Aortic annulus	≥ 18 mm ≤ 25mm ≥	20 mm ≤ 29 mm
Access site	Transfemoral, Transapical	Transfemoral, Subclavian, Direct Aortic

treatments were similar with respect to mortality, reduction in symptoms, and improved valve hemodynamics, although paravalvular regurgitation was more frequent after TAVR and was associated with late mortality. There was a higher stroke rate in the TAVR group compared to the surgical group.

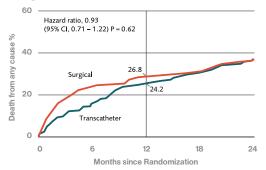
In the PARTNER B study, patients with inoperable severe aortic stenosis (Cohort B; n = 358) were randomly assigned to transfemoral TAVR, receiving the SAPIEN valve, or standard therapy, which often included balloon aortic valvuloplasty. According to the second article, one-year follow-up had shown reduced mortality, subsequent hospitalizations, and associated symptoms for the patients undergoing TAVR. At two years, the advantages in terms of decrease in mortality and an improvement in valve symptoms and hemodynamics were sustained.

Mount Sinai is a principal site for the evaluation of the CoreValve, which is available only to patients enrolled in the CoreValve U.S. Pivotal Trial. The SAPIEN valve is now approved by the Federal Drug Administration (FDA) for implantation in extreme-risk inoperable and high-risk patients. In fact, the first CoreValve procedure in the United States was performed at Mount Sinai, 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. His aorta was highly calcified, and CoreValve implantation was deemed the only option to prolong his life. This patient is alive and well more than two years after the TAVR procedure.

TAVR vs. Standard Treatment @ 2-Yrs Mortality in Partner Trial Cohort B



Transcatheter vs. Surgical Aortic-Valve Replacement in High Risk Patients: Partner Trial Cohort A



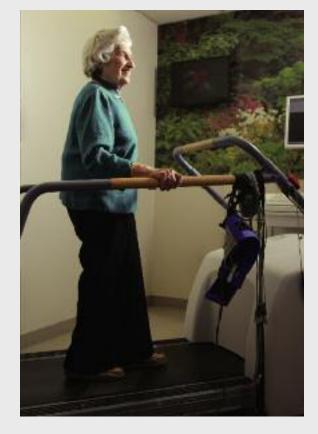
"He called me about a year and a half later – called me personally!"

Patient:	Aleida Keesing 94-year-old female
Diagnosis:	Severe diastolic heart failure, severe aortic valve calcification
Treatment:	Transcatheter aortic valve implantation using 31mm CoreValve

"In 1990, when I was the primary caregiver for my very sick husband, I had a heart attack. After the trauma of losing him, in 2007, there wasn't much left of me. My cardiologist at Mount Sinai, Dr. Arthur Weisenseel, put me on a restricted diet, prescribed various medications and called in a cardiovascular surgeon, who said that my aortic valve was extremely calcified, but there wasn't much he could offer me in terms of treatment.

"I felt better for a while, but by 2010, I was failing. My feet were terribly swollen and painful, and if I went outside, the wind would take my breath away. Dr. Weisenseel decided to call in a colleague at Mount Sinai, Dr. Samin Sharma.

"Dr. Sharma performed valvuloplasty, which he said was the best therapy available for me at that time, and my daughter remembers that he came out of the Cath Lab when the procedure was over and said that my valve was now 90 percent cleared of calcification and he thought it would give me two more years. He called me about a year and a half later – called me personally! – and said, 'The time has come that the valvuloplasty is no longer holding.' He was right.



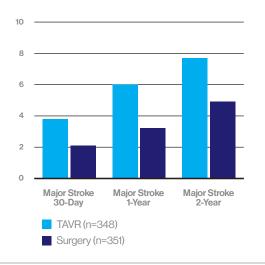
"In April 2010, Dr. Sharma did a second valvuloplasty, putting in a stent this time, and afterward, he said, 'We are involved in clinical research here at Mount Sinai, and there may be a trial procedure that is right for you.' He didn't forget me. In May, he called again and asked me to come in for some testing. I didn't qualify for the first trial, but I did for the second. On May 29, I was the 49th patient at Mount Sinai to receive the Medtronic CoreValve.

"I feel so much better now. Life is worth living again, thanks to Dr. Sharma's personal attention to my case, and his genuine concern. My son and daughter join me in expressing our heartfelt gratitude to Dr. Sharma — a brilliant physician and an exemplary human being."

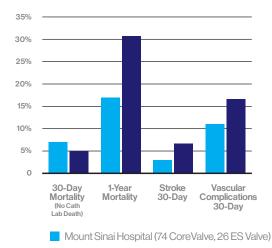
The CoreValve and the SAPIEN valve are comparable in many ways, although the SAPIEN requires a large 22-French or 24-French sheath, compared to 18-French with the CoreValve. Hence, the CoreValve can be used in many patients whose anatomy cannot accept a 22F or 24F sheath. At Mount Sinai we weigh the choice of a valve on a case-by-case basis. Because we are the only hospital in the New York metropolitan area implanting both the SAPIEN and the CoreValve, patients with aortic stenosis are often referred here for treatment.

By November 2012, 100 transcatheter aortic valve replacement (74 CoreValve® and 26 Edwards Sapien Valve® (ES)) procedures had been performed at Mount Sinai, with impressive results — even better results than were achieved in the PARTNER Trial. In a comparison of Mount Sinai's first 100 cases with patients in Cohort A and Cohort B of the PARTNER Trial who received TAVR

PARTNER Trial Cohort A: Stroke at 2 Year



TAVR Experience at Mount Sinai Heart First 100 Cases Mount Sinai Hospital vs. PARTNER TRAIL



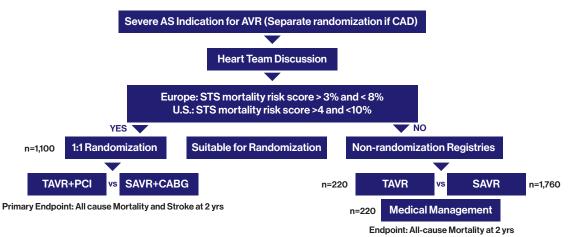
PARTNER Trial (179 Trial B, 348 Trial A)

(Cohort B, n = 179; Cohort A, n = 348), while 30-day mortality at Mount Sinai was 7 percent compared with 5 percent (with no Cath Lab deaths), one-year mortality was only 18 percent at Mount Sinai compared to 30.7 percent in the PARTNER Trial, and 30-day stroke and vascular complications were 3 percent versus 6.7 percent and 11 percent versus 30.7 percent, respectively.

Currently, the CoreValve TAVR procedure is being offered to intermediate surgical risk patients under the SURTAVI trial.

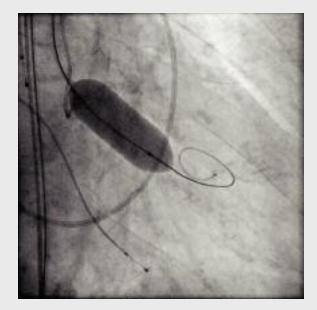
Interventionalists at Mount Sinai frequently perform balloon aortic valvuloplasty, which involves threading a balloon from the femoral artery and open the stenosed valve. This is usually a temporary measure as the valve tends to narrow again in 3-6 months.

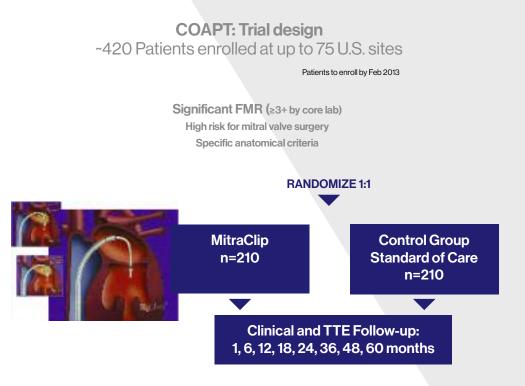
Mount Sinai investigators are also engaged in developing methods to treat other valve diseases using minimally invasive, catheter-based techniques. When mitral regurgitation (MR), a commonly encountered valve disorder, is present, blood flows backward through the



CoreValve US Pivotal SURTAVI Trial

mitral valve when the heart contracts. This reduces the amount of blood that is pumped out of the body. Therapies for percutaneous reduction of mitral regurgitation have shown promise in early clinical trials. The Evalve® Cardiovascular Valve Repair System uses a clip to limit the mitral leaflet movement. Results in the EVEREST (Endovascular Valve Edge-to-Edge Repair Study) Trial of mitral clip versus surgical mitral valve repair have been encouraging. The mitral clip will undergo an FDAsponsored trial (the COAPT (Clinical Outcomes Assessment of the MitraClip Percutaneous Therapy for High Surgical Risk Patients) Trial), which will evaluate the role of the clip against the standard of care in patients with severe MR of functional type and not suitable candidates for traditional mitral valve repair.





Innovations Annapoorna S. Kini, MD, MRCP, FACC



Annapoorna S. Kini, MD, MRCP, FACC

Director, Cardiac Cath Lab & Intervention

Director, Interventional Cardiology Fellowship Program

Coronary Bifurcation Lesions; the Dedicated Bifurcation Stent

Coronary bifurcation lesions, or blockages of the main artery of the heart at a side branch, are fairly common, accounting for 15 to 20 percent of all percutaneous coronary interventions. About 70 percent of left main lesions are bifurcation lesions. Effective treatment of bifurcation lesions has long posed a considerable challenge for interventional cardiologists; their management is associated with a greater number of complications, lower procedural success, and higher rates of restenosis.

Because there are nearly endless anatomic and morphologic bifurcation lesion types, there is not a single "best" interventional approach. One approach has been to perform balloon angioplasty of both the main and the side branch and then to deliver a stent to the main branch only. Another is the provisional side branch stenting strategy: try one stent in the main branch and if deemed necessary use a second stent in the side branch. Yet another approach, known as the routine side branch stenting strategy, is to deploy two stents, choosing among varying techniques.

With T-stenting, the first stent is deployed in the side branch and a second is deployed in the main vessel, across the side branch. With reverse T-stenting, as the name implies, the first stent is deployed in the main vessel, across the side branch, and the second stent is advanced through the main vessel stent and deployed in the side branch. With the kissing stent technique, two stents are advanced into the main vessel and side branch and deployed simultaneously. In the crush technique, two stents are deployed simultaneously in the main vessel and side branch, with the stent in the side vessel being more proximal and being "crushed." Even in this era of drug-eluting stents, however, there is danger of restenosis of the side branch.

A dedicated bifurcation stent that was recently developed has the potential to revolutionize the intervention of bifurcation lesions: the Tryton® Side Branch Stent. It is a slotted-tube cobalt chromium stent with a side branch region, a transition zone and a main vessel region. It is used in conjunction with standard interventional equipment and standard techniques. When it is positioned at the lesion site, a conventional drug-eluting stent is placed inside the Tryton stent, in the main branch only.

The Tryton stent is the subject of an international, 67-site, 704-patient randomized trial, in which Mount Sinai Heart is a major participant. This pivotal study will compare the Tryton stent in the side branch with conventional provisional stenting (balloon angioplasty) in the side branch, with both arms of the trial utilizing a standard drug-eluting stent in the main vessel. The primary endpoint of the study is target vessel failure at nine months. A secondary endpoint is percent diameter stenosis at nine months in the side branch vessel.

"Thanks to Dr. Kini and Mount Sinai, I can say I have outrun heart disease."

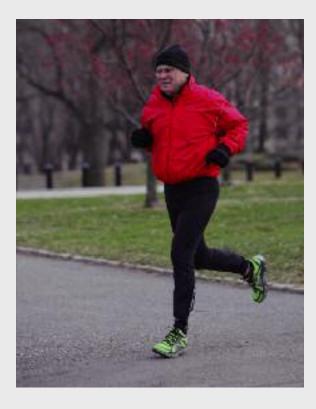
Patient:	William Swan 68-year-old male
Diagnosis:	Stable angina pectoris, 1 VCAD of LAD
Treatment:	Successful DES of Proximal LAD

"I have always been a pretty active guy, exercising regularly, taking care of myself, but three years ago I woke up in the middle of the night with chest pain. It wasn't terrible — I thought it might be muscle pain from working out the day before, or maybe just indigestion.

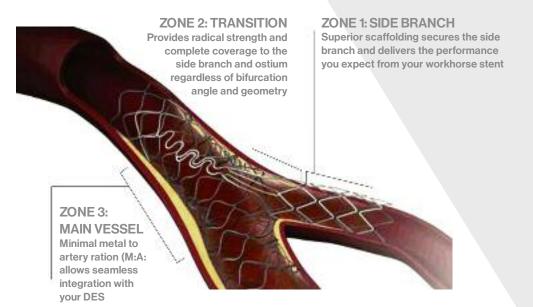
"I did go back to sleep, and when I woke up the pain was gone. I got on my bicycle, which was on a trainer in my apartment, and suddenly the pain was back — and it was severe. My wife and I hurried downstairs and took a cab to the emergency room at Mount Sinai.

"I had an EKG, they took some blood, and then they sent me upstairs for a stress test. I was feeling better, so I was surprised when suddenly, without getting the stress test, I was being rushed to the Cath Lab. I found out later that tests had shown that I was half an hour away from a massive coronary.

"That's when I met Dr. Kini, who exuded calm and confidence. She explained the procedure, and I wasn't nervous at all. She found the blockage and implanted a stent, and I went home after one night in the hospital.

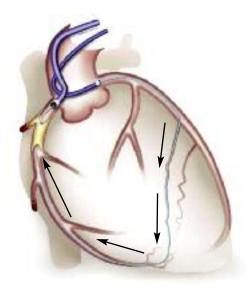


"I guess you're always a bit uneasy about your heart after a close call, and not long after the procedure I went back to Mount Sinai's emergency room. I saw Dr. Kini again, and she gave me a bit of gentle teasing about my worries, but she reassured me that my heart was fine. Since then I've lost about 30 pounds, and I exercise regularly. Thanks to Dr. Kini and Mount Sinai, I can say I have outrun heart disease."





Retrograde Wire Technique of CTO Recanalization



The Tryton stent is commercially available in Europe, Russia and the Middle East, and results overseas are very encouraging. More than 6,000 stents have been implanted, and data from more than 1,000 registry patients in Europe treated with the Tryton stent is already challenging provisional stenting outcome statistics, with target lesion revascularization of 4 percent and thrombosis of 0.5 percent at one year. With its innovative design, the Tryton stent may provide interventional cardiologists with the most effective tool yet to treat these complex lesions.

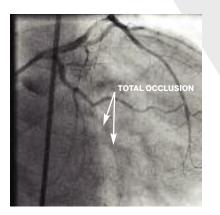
Update on Chronic Total Occlusion

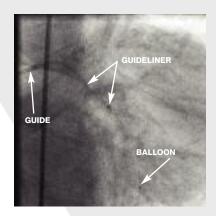
A chronic total occlusion (CTO), found in 15 to 20 percent of all patients undergoing coronary angioplasty, is a complex blockage of a coronary artery that has existed more than three months. Several factors influence the likelihood that the interventionalist will succeed in opening a CTO on the first attempt, including the length of the lesion, its duration and the presence or absence of calcium. The most experienced, highly skilled interventionalists have not been able to raise the firsttime success rate above 80 percent.

This year, however, two technological advances have led to a significant improvement in the success rate to 85 percent or even higher at the first attempt to open a CTO. They are the "mother-and-child" catheter and the development of smaller and smaller angioplasty balloons.

Insufficient back-up support from the guiding catheter often leads to the failure to deliver the stent across the target lesion during percutaneous coronary intervention, particularly if the artery has a calcified, tortuous anatomy. Deep-vessel intubation with the guiding catheter may overcome the problem, but there is a risk of coronary dissection. The new "mother-and-child" (Guideliner) system comprises a flexible-tipped, long catheter (the child) that is advanced from within a standard guiding catheter (the mother), providing enough back-up support to deeply intubate the target vessel. This system improves delivery of the balloon for predilation and subsequent stent delivery in CTOs. Balloon diameter is very important in coronary angioplasty. The diameter of today's tiniest, most delicate angioplasty balloon, which was once no less than 2.0 mm, is now as small as 1.2 mm. This is a valuable weapon in the interventionalist's arsenal. A combination of the Guideliner system and small balloons has improved our success rate with CTOs.

If the first attempt to open a CTO is unsuccessful, either an antegrade or a retrograde approach can be used on the second try. The antegrade approach has been the traditional method of intervention for those patients who meet the guidelines in a CTO. With the technique of retrograde recanalization, the blockage is penetrated from both ends. The second-time success rate for the CTO here at Mount Sinai is now approaching a remarkable 90 percent.

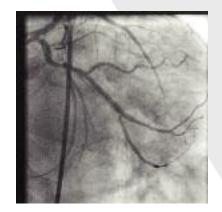




Advancement of Balloon Catheter over wire with help of Guideliner



Post PTCA



Final result Post Stenting

Innovations Pedro R. Moreno, MD, FACC



Pedro R. Moreno, MD, FACC Director, Translational Research, Cardiac Cath Lab



Vulnerable Plaque

Evolving Trends in High-Risk Plaque

High-risk plaque is defined as a coronary lesion, usually non-flow limiting, but prone to develop coronary thrombosis, leading to unstable angina, acute myocardial infarction or sudden cardiac death.

Traditionally, we have focused on high-risk plaques suitable for plaque rupture, which are responsible for 60 to 70 percent of coronary thrombosis. In addition to plaque rupture, we have plaque erosion, responsible for 30 to 35 percent, and calcifying nodules, most commonly seen in elderly patients and responsible for the minority of thrombotic events (less than 10 percent).

During 2012, there were new findings in all three areas. For lesions precipitating plaque rupture, we now know that composition is not the only contributor to thrombosis; two additional factors, plaque burden and minimal luminal area, play a synergistic role in precipitating clinically relevant cardiovascular events. As such, the traditional concept of a thin-cap fibroatheroma (TCFA) is now enriched by two additional features, a large plaque burden (greater than 70 percent) and decreased luminal area (less than 4.0mm²). This suggests that the field may be evolving toward detecting moderate to obstructive lesions, underestimated by angiography. They will certainly benefit from objective data using fractional flow reserve (FFR). Yet to be confirmed will be the detection of coronary events in large-plaque-burden, TCFA plaques with borderline FFRs (0.8 to 0.85).

A second important and clinically relevant finding in large lipid-rich plaques evolved simultaneously from multiple observational and prospective studies documenting significant changes in plaque composition after aggressive statin therapy. Excellent sequential analyses performed using computed tomography angiography (CTA), IVUS (intravascular ultrasound) derived virtual histology, optical coherence tomography (OCT) and near-infrared (NIR) spectroscopy show changes in plaque phenotype toward less lipid atheroma volume, less IVUS-derived TCFA, increased fibrous cap thickness and significant reductions in lipid core burden index.

A single-center prospective, randomized study, the YELLOW trial, performed at Mount Sinai Hospital in obstructive lesions (FFR less than 0.8), tested this hypothesis using rosuvastatin (40 mg) versus standard of care. Lipid core burden index was significantly reduced (33 percent) after seven weeks of therapy, as documented by near-infrared spectroscopy. This was the first study to document intracoronary lipid core reductions in obstructive lesions.

In the area of plaque erosion, a study published in September 2012 in the *Journal of the American Medical Association (JAMA)* documented dramatic increases in coronary thrombosis in females below the age of 60, leading to ST-segment elevation myocardial infarction (STEMI), from 3 to 11 percent, associated with significant increases in smoking, from 37 to 73 percent, in this same group of females. As such, plaque erosion appears to be playing a pivotal role in acute myocardial infarction in premenopausal females. In this group of patients, during acute treatment in the cath lab, manual thrombectomy may yield a nonobstructive, almost clean angiogram

"What struck me was that Dr. Moreno really listened to me. You don't get that too often in today's healthcare environment."

Patient:	Harold Wagner 69-year-old male
Diagnosis:	90 percent stenosed LAD artery
Treatment:	Intervention of LAD-proximal with
	implantation of drug-eluting stent

"My father and my uncle died young from heart disease, and my brother had bypass surgery five years ago. I've always been aware of my family history, and I've done what I could to counteract it – exercising regularly, hiking and biking, and eating healthy foods.

"In the fall of 2012, I began to have some vague symptoms: heart palpitations, a feeling of heaviness in my chest, some mild pain in my upper left arm and my jaw. I saw a cardiologist in Connecticut who sent me for a stress test and decided my problems had to do with the blood pressure medication I had been taking for a dozen years. A second opinion from another cardiologist agreed with the first. That's when my brother, Bill, said, 'Let me call Dr. Pedro Moreno, at Mount Sinai.'



"Dr. Moreno called me that evening, and I told him about my family history, my symptoms, my visits to other doctors. He said that he wanted to see me, and I went down to Mount Sinai two days later.

"What struck me was that Dr. Moreno *really listened to me*. You don't get that too often in today's healthcare environment. He said that catheterization was the only way to know what was going on inside my heart, and that was what he recommended. He performed the procedure, and sure enough, he found that my LAD [left anterior descending] artery was 90 percent blocked. He cleared the blockage and implanted a drug-eluting stent.

"Dr. Moreno reassured me that aside from the blockage my heart is healthy and strong. I've had some issues with side effects of the blood-thinning medications, and he has continued to be available to me. I hope never to require another catheterization, but I have a cardiologist for life."

immediately after thrombus aspiration. This angiographic finding has generated controversy regarding optimal treatment (stent versus no stent). More data is needed, but there are cases in which stenting may not be absolutely needed.

Finally, calcium nodules may also be relevant in the elderly population in which optimal vessel wall preparation with cutting balloons or Rotablator[®] may be necessary for adequate stent expansion and good opposition.

In general, the cath lab-related detection of vulnerable plaques is now focusing on large-lipidpool, positively remodeled TCFAs with some degree of lumen compromise. The incidence of these lesions is about 5 percent, but the incidence of vascular events per lesion is as high as 17 percent at three years. Considering that the new-generation stents' coronary event rate may be below 10 percent at three years, these lesions may be suitable for a randomized trial to test the hypothesis that coronary stenting may reduce events.

Aggressive smoking-cessation efforts are more important than ever, especially those directed toward females under the age of 60. Noninvasive approaches toward detecting the patient at risk for plaque rupture and thrombosis, including coronary calcium scores, carotid threedimensional ultrasound, ankle brachial index (ABI) testing and in some cases CTA, may evolve as valid strategies that will obviate the need to go into the coronary arteries.

These efforts require massive investments, both in public education and in the development of new diagnostic approaches.

Innovations Michael Kim, MD, FACC



Michael Kim, MD, FACC Director, Coronary Care Unit

Prevention of Acute Kidney Injury

Patients with chronic renal insufficiency pose a significant challenge for the interventional cardiologist. Cardiac catheterization requires injection of a contrast agent, or dye, which can worsen kidney function. Furthermore, several articles in medical journals, including an article in *Kidney International*, coauthored by Roxana Mehran, MD, of Mount Sinai Heart, have reported that worsening kidney function after catheterization can lead to higher mortality. ("Contrast-Induced Nephropathy: Definition, Epidemiology, and Patients at Risk," 2006)

For patients with advanced kidney disease who are referred to the catheterization laboratory, there are many considerations. The first is whether catheterization should be performed at all. The benefits to the patient with chronic renal insufficiency should clearly outweigh the risks of injecting the contrast agent. *This is a very important decision*, which must be made with input from the referring physician, the interventionalist and the patient's nephrologist.

If it is decided that catheterization should be scheduled, it is the interventionalist's duty to mitigate, as much as possible, the harmful effects of the contrast medium. The oldest and still the most effective means of preventing damage to the kidneys after the procedure is *hydration*. We recommend hydrating with normal saline solution for at least 6 to 12 hours prior to the procedure for patients with very advanced kidney disease, and at least six hours prior to the procedure for patients with mild to moderate kidney dysfunction. Hydration after the procedure is not as valuable as prehydration.

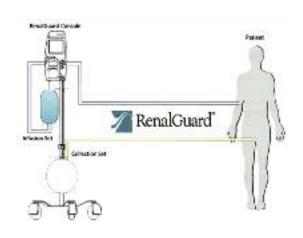
Finally, before the procedure, the interventionalist should do preliminary research — reviewing old films, knowing the whereabouts of bypass grafts and any coronary anomalies. This can shorten the case and lessen the amount of dye used. During the procedure, it is important to be cognizant of how much dye is being used and how many pictures are being taken.

RENAL GUARD Device to Prevent Contrast Injury

Purpose: Provide Continual and Equivalent I:O fluid replacement (NS)

Recruitment: To enroll subjects with moderate to severe kidney impairment who are at high risk of acquiring CIN who are scheduled to undergo a non emergency procedure that anticipates using a total of at least 75 ml of radio-contrast media.

	RANDOMIZED	
CONTROL	RENALGUARD DEVICE	
*Bolus preprocedure	*Bolus and IV LASIX preprocedure	
*IV saline at set rate (cc/kg)	*IV I/O fluid replacement (saline) by urine weight cc per cc. (requires Foley Catheter)	
Hydration through out the procedure and for 4 hours post last dye. Follow Up/Labs: 3 hrs, Day 1, 2, 3, 7 and Day 90		



"Dr. Kim is a wonderful person, very kind and compassionate."

Patient:	America Medina, 73-year-old female
Diagnosis:	Stable angina, 80% stenosis in RCA
Treatment:	Successful DES of RCA

"I have diabetes, high blood pressure, high cholesterol and a family history of heart disease, so I'm glad I have Dr. Michael Kim and Mount Sinai. I also have emphysema and obstructive pulmonary disease (COPD). I have received four stents in all, two of them in May of 2012. In the fall I was having some shortness of breath and chest pain, and I came in so that Dr. Kim could perform another catheterization procedure.

"Dr. Kim is a wonderful person, very kind and compassionate. I'm feeling pretty good now, but with my health issues it's reassuring to know I am under his care. And did I mention that I am also a cancer survivor – breast and thyroid?

"All my doctors are here, and all are great. I've been coming to Mount Sinai since I was a teenager, and I wouldn't think of going to another hospital."



Mount Sinai is a participating center in a number of clinical trials examining strategies to prevent contrast-induced nephropathy (CIN), the most promising of which is PLC Systems' CIN-RG trial, which is studying the efficacy of its RenalGuard Therapy[®] and RenalGuard System[™]. In fact, I enrolled the first patient in the study here at Mount Sinai. The system's operating principle is that high-volume flow beginning with forced diuresis and up to 5 liters of fluid during the catheterization will clear the kidneys of the dye and its toxic effects.

Other agents that seemed to hold promise for preventing kidney damage in 2011 were Mucomyst (acetylcysteine) and sodium bicarbonate. Further study showed that neither fulfilled that promise; we mention them only to illustrate that Mount Sinai is well versed in the literature and any developments on this topic. We have performed thousands of procedures on patients with moderate to very severe kidney disease, with the incidence of dialysis extremely rare, and we continue to strive for even better results for our patients.

Innovations Prakash Krishnan, MD, FACC



Prakash Krishnan, MD, FACC Director, Endovascular Intervention

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 3-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, hyperlidemic, 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 3vessel 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.

"Dr. Krishnan and the staff are so excited when I tell them I can walk as far as two miles on the beach. They are like my cheering squad."

Patient:	William Evensen 71-year-old male	
Diagnosis:	Peripheral arterial disease	
Intervention:	Endovascular Intervention of the left	
	superficial femoral artery in the Levant II Trial	

"For years, I've suffered with vascular problems in my legs. I had lowerextremity bypass surgery about 15 years ago, which helped temporarily, but I began feeling worse and worse — I couldn't walk up the slightest incline without severe pain in my legs. I worked delivering food to grocery stores, and I had to retire early because I couldn't carry the boxes any more.

"I was referred to Dr. Krishnan for treatment of my legs, and he ran some tests and found blockages. I came to Mount Sinai and he did the procedure through a small catheter in my leg. I had no significant discomfort and was walking the very next day."

"Now I'm feeling great. As an ex-smoker I have and always will have emphysema, but I can take my new puppy for walks. I'm even thinking about going back to work part time. When I go back to the hospital, Dr. Krishnan and the staff are so excited when I tell them I can walk as far as two miles on the beach. They are like my cheering squad.

"I can honestly say I would be miserable now if it weren't for Dr. Krishnan and his team."



Drug-eluting stents in peripheral arterial diseases

For the peripheral vascular system, evidence on drug-eluting devices is less robust

Drug-eluting balloon trials published						
Author/name	Patient number	Target population	End point	p-value	Drug eluting device better?	
THUNDER Trial	154	IC, CI	Lumen loss at 6 months	p < 0.001	Statistically better	
Werk	87	IC, CI	Lumen loss at 6 months	p = 0.031	Statistically better	

Conclusion

Mount Sinai participation in DEB trials					
Author/name	Mount Sinai patient number enrolled	End point			
Levant II	27	Primary patency at 12 months			
InPact SFA	20	Primary patency at 12 months			

Innovations George Dangas, MD, PhD, FACC, FSCAI



George Dangas, MD, PhD, FACC, FSCAI

Director of Cardiac Innovation, Zena and Michael A. Wiener Cardiovascular Institute

Catheter-Based Renal Sympathetic Denervation for Resistant Hypertension: SYMPLICITY HTN-3 Trial

Resistant hypertension is defined as blood pressure that remains uncontrolled despite treatment with three or more medications. Resistant hypertension is a major comorbidity of cardiovascular disease that is associated with many problems, including heart attack, stroke and heart failure. Control of blood pressure improves survival as well as decreasing the risk of all these complications, but in this segment of the population we have not been able to normalize the blood pressure despite our best efforts.

The kidneys are called the thermostat of blood pressure, and today 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.

An intervention based on this new understanding is called catheter-based renal sympathetic denervation; it is offered to patients through the Symplicity HTN-3 clinical trial, in which Mount Sinai is a vanguard center. Patients undergo catheterization and angiography to ascertain that there are no blockages in the renal arteries. Then a form of radiofrequency energy is applied to four or five areas within each artery, with a small, flexible catheter, debilitating the abnormal circuit. Typically the procedure, which is performed under local anesthesia, is over in less than an hour.

The trial, which began late in 2011, will run through 2013. The study is designed so that the majority of subjects will be treated immediately and the

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Standard interventional technique 4-6 two-minute treatments per artery

rest will be treated in six months if their blood pressure continues to be resistant. The procedure and the experimental catheter are already approved in Europe, and results are encouraging; the same is true here at Mount Sinai for the 15 patients enrolled in the active arm of the trial.

It is very important for cardiologists and internal medicine specialists to learn about this intervention, with its potential to help this difficult-to-treat population. Many patients have stopped visiting their doctors because until now they have been offered no treatment options that had any benefit. To spread the word, our researchers are traveling to practices affiliated with Mount Sinai Heart, where modified procedures permit screening of patients with resistant hypertension.

There are many layers of benefit to offering the screening outside the hospital. First, there is a wider pool of potential candidates for the trial. If they qualify for the procedure, it will

Renal Nerve Anatomy Allows Catheter Based Radio-Frequency Ablation of RA

"Isn't it marvelous, the way the finest doctors all over the world are able to collaborate and exchange patient files today!"

Patient:	Alain Lessel-Kirili,		
	66-year-old male		
Diagnosis	l Instable angina coronar		

Diagnosis: Unstable angina, coronary atherosclerosis of native vessel

Treatment: Successful intervention of left main and circumflex arteries; implantation of drug-eluting stent

"My trouble with my heart began in 2005, when I was in France, my native country. I was treated by a cardiologist there, and when I needed a cardiologist in New York, where I live most of the year, he was able to recommend two doctors at Mount Sinai: Dr. George Dangas and Dr. Roxana Mehran. Isn't it marvelous, the way the finest doctors all over the world are able to collaborate and exchange patient files today!

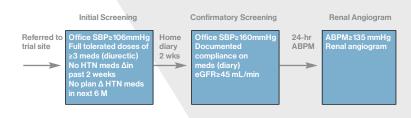
"I went to see Dr. Dangas, and he recommended catheterization and the placement of a stent, which he performed in May of 2012. Then in November he implanted another stent. I am an artist with an interest in creating archetypal, organic forms, and while I was lying on the table in the Cath Lab during the procedure, there on the screen I saw that the angiogram of my living, beating heart replicated my wire sculptures!

"Expressing my surprise to Dr. Dangas, I invited him to come to my studio and see my work, and he accepted. He told me that he has an interest in the aesthetics of interventional cardiology, and I understood. Both of us are artists, in our own fields. We had a wonderful conversation, about art, not my heart! You might call it a meeting of creative minds."

be performed at Mount Sinai, but they can receive follow-up care in their own communities. Then there is the opportunity to educate the personnel in the satellite offices, including doctors, nurses, nurse practitioners and physician's assistants, in the procedures and goals of the study. These interactions will communicate to our network doctors the robust systems we have in place, and the rigorous clinical research standards we adhere to, and they will engender a spirit of collaboration. We are working together as a team, for the good of our patients.



Symplicity HTN-3 Trial of RF Ablation: Referral to Randomization Steps



Innovations Joseph M. Sweeny, MD



Joseph M. Sweeny, MD Associate Director Interventional Cardiology Fellowship

Radial artery access



Transradial Percutaneous Coronary Intervention

In the United States, the vast majority of percutaneous coronary stent procedures (PCI) are performed via the groin (the transfemoral approach), while very few are performed via the wrist (transradially). New medications and vascular closure devices have helped minimize the dangers of the transfemoral approach, mainly bleeding and vascular damage. Until recently, the transradial approach has been used primarily for patients who are not candidates for the transfemoral approach: obese patients, or those with small or diseased peripheral arteries. However, there now seems to be a momentum of change toward the transradial approach for PCI.

Another consideration is exposure to ionizing radiation. With the transradial approach, there may be an increase in fluoroscopy time and exposure to both the operator and patient due of the technical challenges posed by that approach, particularly for less experienced operators.

This analysis, among other randomized studies, has led interventionalists worldwide to begin moving away from the transfemoral and toward the transradial approach. Certain advantages to patients in general with the transradial approach have been recognized for some time. After the procedure, they don't have to lie flat for two hours or more; they can sit up, eat, urinate in the normal way and often go home the same day.

There are, however, some disadvantages, to both patients and interventionalists. Many interventionalists have been trained to operate using the transfemoral approach, and there is a somewhat steep learning curve with a new approach. The transradial approach is a bit more difficult with complex cases such as bifurcation lesions requiring larger guiding catheters or atherectomy devices, or tortuous anatomy. For STEMI patients, on whom the new data analysis focused, time is of the essence. "This is an emergency situation, and radial PCI should be attempted in [STEMI] patients only by experienced operators," emphasized Dr. Sameer Mehta. "The radial approach should be learned in stable patients first, graduating to non-STEMI ACS, then to STEMI."

Another consideration, mainly for the interventionalist, who works in the cath lab every day, is exposure to ionizing radiation — an exploding topic today in health care. The cath lab is an area where exposure is particularly high, perhaps higher than in any other area of the hospital. With the transradial approach, there may be an increase in fluoroscopy time and exposure to both the operator and patient due of the technical challenges posed by that approach, particularly for less experienced operators.

In conclusion, it can be said that for a nonemergent patient, the transradial approach has many advantages, mainly relating to less risk for bleeding, comfort, convenience and a quicker recovery. For a STEMI patient, in a cath lab with fully evolved procedures for transradial access, in the hands of an interventionalist who is fully trained and expert, the transradial approach can be lifesaving.

Robert Pyo, MD

Vascular Closure Devices

PCI requires an arterial puncture (often of the femoral artery) to allow the interventional cardiologist to insert a specialized tube called a sheath and gain access to the vascular tree. When the sheath is removed after the intervention, the puncture site has to be treated to stop the bleeding. There are two ways to accomplish hemostasis in patients who have undergone a procedure with femoral artery access: manual compression and use of a vascular closure device (VCD).

Manual compression was the standard of care until the early 1990, when, because of concerns about bleeding complications, VCDs were developed. There are two major VCD categories: 1) immediate active; and 2) passive. VCDs in the first category employ sutures, anchored plugs and metal clips to provide almost immediate hemostasis. VCDs in the second category utilize extrinsic compression with the assistance of prothrombotic patches or stimulation of the puncture site with a wire, usually resulting in hemostasis within five minutes. Devices that are based on sutures or anchored plugs are often chosen because of their ease of use and their immediate effect.

Although concerns over vascular access site complications inspired the development of VCDs, there have been mixed results when these devices have been compared to manual compression; it is not clear whether their use reduces overall complication rates. Although bleeding-associated complication rates are reduced, it appears that a VCD-specific complication such as acute vascular injury negates any net advantage provided by use of these devices.

Despite mixed results from studies examining the incremental advantage of VCDs over manual compression, these devices are used commonly at Mount Sinai, for various reasons. These devices unquestionably allow earlier ambulation for patients after a percutaneous procedure. Early ambulation will become more important as hospitals adopt a policy of same-day discharge after PCI. Additionally, complex interventions require insertion of multiple and often larger-caliber sheaths. As an example, sheaths that are used to insert aortic valves percutaneously can be as large as 9.2mm in outer diameter. Removal of larger sheaths absolutely requires use of closure devices, in particular, suture-based ones. Manual compression will not close the arterial puncture after removal of a larger sheath.

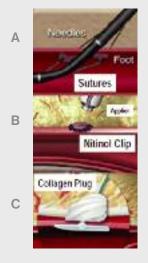
Improved patient comfort is another reason we use VCDs at Mount Sinai. Increasingly, older patients are presenting for procedures; these patients are more likely to have back and other problems related to degenerative joint disease. Many cannot lie immobilized for a prolonged period of time without significant discomfort. Early mobility is essential in these patients.

At Mount Sinai, VCDs are used quite commonly, but appropriately. We utilize many kinds of devices, and due to our very high clinical volume, the operators are very experienced. The use of a particular closure device is tailored to the specific anatomy and clinical background of each patient. Our experience and the use of a patient-specific, individualized approach contribute to a very low VCD-associated complication rate at our institution.



Robert Pyo, MD Assistant Professor of Medicine, Cardiology and Radiology

Examples of Immediate Active VCD



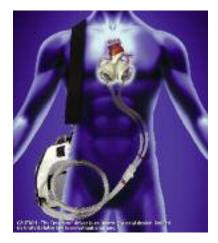
A - Perclose (Abbott Vascular) Suture B - Starclose (Abbott Vascular) Clip

C - Angioseal (St. Jude Medical) Plug

Innovations Ajith Nair, MD



Ajith Nair, MD Director, Coronary Care Unit



SynCardia Freedom® Driver

The SynCardia Total Artificial Heart

More than 1,000 patients nationwide have received the SynCardia Total Artificial Heart. But Daquain Jenkins is the first patient in the tristate area to go home from the hospital with the artificial heart pumping in his chest; he left Mount Sinai on October 25, 2012, only two months after it was implanted.

Mr. Jenkins was only in his late twenties when he came to Mount Sinai in 2010, but he was suffering from cardiomyopathy and he had a grim family history; his father had been only in his twenties when he died. He was diagnosed with severe heart failure, received a native heart transplant here at Mount Sinai, and returned to his home in upstate New York.

He did very well at home for the first six months, although he was under a fair amount of stress, with the frequent hospitalization of the oldest of his three children. When he returned to Mount Sinai after a year, in June of 2012, there was no clear evidence of rejection, but his transplanted heart was failing. Even a cough would stress his heart and he would almost pass out.

Because he was so sick, his options were limited. He couldn't wait for another native heart. A left ventricular assist device wouldn't help him, because the right side was failing too, and because he was on immunosuppressive medications and implantation of an LVAD (or an LVAD and an RVAD) would introduce the risk of infection. Recognizing that the patient was days from death, Sean P. Pinney, MD, director of the Advanced Heart Failure and Cardiac Transplant Program, cardiothoracic surgeon Anelehi Anyanwu and coordinator Kim Ashley spearheaded a push to implant the total artificial heart. It would be a first at Mount Sinai.

Mr. Jenkins's native heart was removed and the SynCardia Total Artificial Heart was implanted by Dr. Anyanwu and David Adams, MD, head of cardiothoracic surgery at Mount Sinai. The device pumps up to 9.5 L/min of blood through both ventricles, based on the body's needs. The two artificial ventricles partially fill and then fully eject the amount of blood returned to the heart from the body. During exertion, more blood — up to 30 percent more enters the ventricles. Inside each ventricle is a diaphragm that pumps blood. Vacuum supplied by the pneumatic driver that accompanies the SynCardia heart pulls the diaphragm down to allow blood to enter the ventricle. To eject blood, a pulse of air pushed the diaphragm to the top of the ventricle. The device offers four new valves, and after over a thousand SynCardia hearts have been implanted, no valve has failed.

The patient came through the procedure remarkably well, and was quickly up and about, although he was always tethered to the pneumatic compressor (called "Big Blue"), which was the size of a refrigerator and quite noisy.

"With the Freedom driver, my life is nearly normal."

Patient:	Daquain Jenkins 29-year-old male		
Diagnosis:	Failure of transplanted native heart		
Procedure:	Placement of SynCardia Total Artificial Heart		

"I was feeling really sick when I came back to Mount Sinai in 2012, but I didn't realize that I was near death. The SynCardia Total Artificial Heart saved my life. I felt so much better right after the operation that I didn't mind the noise and the inconvenience of the compressor that was my constant companion. I was very quickly able to walk the halls at a serious pace, with a physical therapist beside me and two nurses pushing "Big Blue" along behind me.



"I have three children, ages 10, 8, and 5. I missed them very much, and of course they missed me and were anxious about me. I was very grateful for the effort at Mount Sinai to get me the Freedom driver so I could go home to Goshen.

"With the Freedom driver, my life is nearly normal. I'm taking online classes in web design, at the Art Institute of Pittsburgh. Carrying the driver in a backpack, I can walk my children to the school bus stop, and I can ride in a car, go to the grocery store and get out in the world. I know that I have more major surgery ahead of me, but my doctors and Mount Sinai are the best. I've been told that a patient lived for four years with the artificial heart, but I'm sure I'll get my donor heart sooner than that. When I get the word, I'll be making a beeline for Mount Sinai."

Because he was so far from home and family, coordinators Kim Ashley and Rachel Flynn worked hard to obtain SynCardia's Freedom[®] Portable Driver, which weighs 13.5 pounds and can be carried in a large backpack, so he could be discharged.

After a few weeks in a transplant living center, Mr. Jenkins went home. He is taking classes online, and the Freedom driver allows him enough mobility "almost" to be leading a normal life. He is back on the heart transplant list, and will receive his new donor heart, when it becomes available, at Mount Sinai — the hospital that gave him a second chance at life.

Innovations Barry Love, MD, FRCPc



Barry Love, MD, FRCPc Director, Congenital Cardiac Catheterization Laboratory Mount Sinai Heart

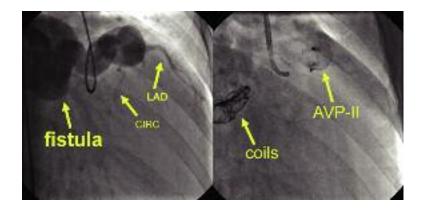
Coronary Artery Fistulas

A coronary artery fistula is a congenital connection between the coronary artery system and a cardiac chamber or the pulmonary artery. Small, insignificant coronary artery fistulas may be found in about one in 1,000 patients undergoing coronary artery angiography. However, about 5 percent of these vessels can progressively enlarge with increasing flow. This may lead to severe enlargement of the feeding "normal" coronary artery, cardiac chamber enlargement, "steal" from the distal myocardium, endocarditis, or when very large, even heart failure symptoms.

When intervention is required, coronary artery fistulas can be closed, either surgically or in the cardiac catheterization lab. Surgery is less attractive, because differentiating the enlarged but essential coronary artery tree from the abnormal vessels on the surface of the heart may be difficult. In the catheterization lab, the combination of diagnostic imaging with radioopaque dye and the ability to occlude the abnormal vessel(s) makes for a more controlled procedure with potentially better outcomes.

A recent patient at Mount Sinai had been diagnosed with a huge coronary artery fistula from the left coronary artery to the right atrium. He had become symptomatic with congestive heart failure and was unable to walk across the room without becoming short of breath. He additionally suffered from worsening leg edema despite the complete cocktail of anticongestive medications, including furosemide, carvedilol and an ACE inhibitor.

He had a loud, continuous murmur upon examination. A CT angiogram clearly showed the huge coronary artery fistula from the left coronary artery taking a very tortuous course draining into the right atrium. All the cardiac chambers were enlarged and the left ventricular function was depressed.



Dr. Love evaluated the images and met with the patient and his wife. "We knew at that point that we might need more than one procedure to achieve closure," said Dr. Love. "In my 17 years in congenital cardiology, I have never personally seen, nor seen reported, a fistula so large." The first procedure was performed from the venous side, attempting to close the exit site of the fistula into the right atrium. Despite placement of several coils, there were multiple sites of egress; although we decreased the flow somewhat, we were unable to close the flow from that approach. "I'm grateful that I found a doctor who was so skilled, so determined, and so committed to helping me."

Patient:	Venku Mandalap, 51-year-old male
Diagnosis:	Coronary artery fistula
Treatment:	Transcatheter closure coronary artery fistula

"About four years ago, I began to notice that my feet and legs were swollen, and I was often breathless. My business is buying and selling companies, and although I was feeling worse and worse, I tried to work through it. Finally, a bad cough sent me to my primary care physician's office.

"He diagnosed bronchitis, and further tests revealed an enlarged heart and a coronary artery fistula. I was prescribed diuretics, but my condition continued to deteriorate. That's when I was referred to Dr. Barry Love.

"I trusted him right away, and although he told me that a procedure to close my coronary artery fistula might not be successful, I decided to continue the journey.

"After the first procedure, Dr. Love told me that it was not successful. He told me that he wanted to try another, larger device, and again, I put myself in his hands.

"After the second procedure I felt better, and this time Dr. Love was satisfied with the result. I continue to feel very well, and I'm grateful that I found a doctor who was so skilled, so determined, and so committed to helping me."



A few weeks later, the patient was brought back to the lab for attempt at occlusion from the arterial side. Because of the large size of the fistula (16-18mm) and the torrential flow, coils would not "hold" from the arterial approach. "We knew that we would need a more robust device that would remain in place despite the high pressure and flow." An 8.5Fr "steerable" Agilis sheath was used as a guide to the coronary artery. An 8Fr guiding catheter was then directed through this sheath down the hugely dilated left coronary artery beyond the origin of the circumflex coronary artery and into the fistula. A 22mm Amplatzer™ Vascular Plug II (AVP-II) was then deployed into the fistula. The AVP-II is a tri-lobed, self-expanding occluder made with a finely woven Nitinol mesh. Angiography during and after deployment of the AVP-II allowed us to be confident that the device was not interfering with flow in the normal coronary arterial tree. After deployment and release of the device, there was only trivial residual flow seen in the fistula.

While this was the largest coronary artery fistula ever seen in our lab, we have achieved a successful functional closure. We continue to see the patient at Mount Sinai at follow-up appointments. His cardiac chambers have returned to normal size and the left ventricular function has normalized. He has come off all of his anticongestive cardiac medications and is now asymptomatic. He has gone from not being able to walk across the room to doing aerobic exercise three to five times a week.

Innovations Roxana Mehran, MD, FACC



Roxana Mehran, MD, FACC

Director of Interventional Cardiovascular Research and Clinical Trials

Lessons Learned from the PARIS Study, One Year Out

A one-year report on the PARIS (Patterns of Nonadherence to Antiplatelet Regimens in Stented Patients) Registry contains some important news for patients with acute coronary syndrome (ACS) and implanted stents, and for their cardiologists as well.

The PARIS Registry is designed to determine how adherent patients are to dual antiplatelet therapy (DAPT); what their mode of cessation was if they are no longer on DAPT; and what the clinical outcomes are that relate to their mode of cessation. Previous studies have only assessed whether patients are on or off DAPT at specific follow-up points or at the time of events. The registry is following 5,033 subjects who received stents, either bare metal or drug eluting. It began late in 2011, and patients were contacted at 30 days, six months and one year. Without any risk of being penalized, they were urged to be truthful about their adherence. The study will conclude late in 2013.

Adherence to DAPT, a prescribed regimen of aspirin and a second anticlotting agent, such as Plavix, is very important for patients with ACS and those undergoing PCI. The AHA and ACC recommend 30 days of DAPT following placement of a bare metal stent, and one full year following placement of a drug-eluting stent. For patients with ACS, one full year is recommended regardless of stent type.

In the study, there were three modes of DAPT cessation: discontinuation, based on the recommendation of the physician; interruption, under guidance of the physician, due to need for surgery (DAPT to be reinstituted within 14 days); and disruption, by the patient, which might be due to bleeding (including DAPT at lower levels than prescribed). Nonadherent subjects were those with DAPT cessation due either to interruption or to disruption. Adherent subjects either remained or DAPT at one year or discontinued based on physician-guided recommendations.

At one year, 19.9 percent, or about 1,004 of the 5,033 patients in the study, were off DAPT. The mode of cessation was disruption or interruption for 12.3 percent, or 620 patients, and physician-recommended discontinuation for 7.6 percent, or 384 patients. In other words, of the patients who were off DAPT by one year, 620 were classified as nonadherent.

DAPT cessation at one year was associated with an increased risk for all adverse events; that association was strongest in the first seven days and attenuated after 30 days. The overall one-year major adverse events were death, 2.2 percent; target lesion revascularization, 4.5 percent; spontaneous myocardial infarction, 1.9 percent; stent thrombosis, 1.9 percent; definite/ probable stent thrombosis, 1.0 percent; major bleed, 2.5 percent; and major adverse coronary event (defined as a composite of death, target lesion revascularization, spontaneous MI and definite/probable stent thrombosis), 7.2 percent.

The interesting finding is that increased risk was entirely attributable to nonadherence; physician-guided discontinuation did not lead to adverse events.

Nurse Innovation

Building a TAVR Program

Surgical aortic valve replacement (SAVR) is the gold standard of treatment for severe, symptomatic AS. It improves symptoms and survival. In clinical practice, however, at least 3 percent of patients do not undergo SAVR due to comorbidities, advanced age and frailty. Transcatheter aortic valve replacement (TAVR) has emerged as a promising alternative for those with high or prohibitive risk for SAVR. To implement this procedure successfully, developing a TAVR program is essential.

Establishing a TAVR program takes significant commitment, investment and full administrative support. This procedure must be performed in specialized heart centers with experience, sufficient volume and a properly trained heart team. Implementing this program requires a multidisciplinary approach and identification of point persons in each department (interventional cardiology, cardiothoracic surgery, vascular, imaging, nursing, administration and research, among other specialties). Prior to initiating the program, physicians must undergo rigorous training with the device companies and all involved staff must undergo procedure and protocol training. Educating staff and developing guidelines are essential elements of our program and contribute to quality care and positive outcomes. A designated research coordinator (or more than one) is necessary for compliance with protocols and accurate data entry. All components of the TAVR team meet weekly to discuss training, protocols, patient review and scheduling.

Identifying potential candidates for this procedure is the first step, and educating the community and referring physicians about our program has facilitated this process. Once a patient has been identified as a possible candidate, a dedicated TAVR nurse practitioner or nurse practitioners educate the patient and family and begin the screening process. Once the screening results are in, they are reviewed and discussed among the team. If the patient is deemed an appropriate candidate, he or she is presented for the appropriate device and a procedure date is scheduled. The TAVR procedure at Mount Sinai Medical Center is performed in a dedicated hybrid Cath Lab. After the procedure, patients are transferred to specialized units with protocols and properly trained staff. A system has been put in place to ensure appropriate follow-up and ongoing communication with the referring physicians.

The TAVR program at Mount Sinai Medical Center began in December 2010 when we became a site for the Medtronic CoreValve U.S. pivotal trial and implanted the first CoreValve in the United States. We also offer the Edwards SAPIEN device, now FDA approved for commercial use. As of January 2013, Mount Sinai was the only center in New York City offering both valves. Our multidisciplinary team strives to continue to improve our program and ensure positive outcomes. No single person makes this program a success; it is a true team effort.

The ability to offer both valves has allowed us to accommodate a greater number of patients.



Sureka Patel, MS ANP-C and Melissa Mattimore, MS, ACNP-BC

Research and Clinical Trials

In addition to unprecedented clinical success, the Mount Sinai Heart Catheterization Lab leads the field of Interventional cardiology in conducting its own investigator-initiated trials and participating in numerous multicenter trials. The most important research developments of 2012 are the CoreValve and Tryton Side Branch Stent clinical trials. Also, key scientific publications on various interventional outcomes from our huge database repository of over 42,000 patients since the year 2000 continue to advance the field of interventional cardiology in a safe manner.

Top 10 Major Publications: Mount Sinai Cardiac Cath Lab

1. Creatine kinase-MB elevation after coronary intervention correlates with diffuse atherosclerosis, and low-to-medium level elevation has a benign clinical course: Implications for early discharge after coronary intervention. Kini A, Marmur J, Kini S, Dangas G, Wallenstein S, Cocke T, Brown E, Ambrose J, Sharma S. *J Am Coll Cardiol*, 34:663, 1999.

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 to 15 months' follow-up. We also established by careful follow-up that patients with elevated CK-MB but declining value can safely be discharged home without any untoward events.

2. A simplified approach to bifurcation lesions in medium-to-large-size vessels: Simultaneous kissing stents (SKS) technique. *Am J Cardiol*, 94: 913, 2004. Also SKS-DES in large bifurcation lesions. Sharma S, Ahsan C, Lee J, Kim M, Fisher E, Steinhamer A, Kini A. *Cathet Cardiovasc Interv*, 65:10, 2005.

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

3. Changing outcomes and treatment strategies for wire-induced coronary perforations in the era of bivalirudin use. Kini A, Rafael O, Sarkar K, Rajdev S, Jakkula M, Mares A, Kaplish D, Krishnan P, Kim M, Sharma S. *Cathet Cardiovasc Intervent*, 74:700, 2009.

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 it occurred with bivalirudin use had a benign course compared to its occurrence with heparin. This can be explained simply on the basis of short bivalirudin half-life.

4. Outcomes of patients discharged the same say following percutaneous coronary intervention. Patel M, Kim M, Karajgikar R, Kodali V, Kaplish D, Lee P, Moreno P, Krishnan P, Sharma S, Kini A. *J Am Coll Cardiol Intv*, 3:851, 2011.

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.

5. Impact of the everolimus-eluting stent on stent thrombosis: A meta-analysis of 13 randomized trials. Baber U, Mehran R, Sharma S, Brar S, Yu J, Suh J, Kim H, Park S, Kastrati A, Waha A, Krishnan P, Moreno P, Sweeny J, Kim M, Suleman J, Pyo R, Wiley J, Kovacic J, Kini A, Dangas G. *J Am Coll Cardiol*, 58:1569, 2011.

Clinical Implications: This meta-analysis of 13 randomized trials involving over 17,000 patients showed that XIENCE V DES had 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 drug-eluting stents in the U.S.

6. Strategies for multivessel revascularization in patients with diabetes. Farkouh M, Domanski M, Sleeper L, Siami F, Dangas G, Mack M, Yang M, Cohen D, Rosenberg Y, Solomon S, Desai A, Gersh B, Magnuson E, Lansky A, Boineau R, Weinberger J, Ramanathan K, Sousa J, Rankin J, Bhargava B, Buse J, Hueb W, Smith C, Muratov V, Bansilal S, King S 3rd, Bertrand M, Fuster V, FREEDOM Trial Investigators. *N Engl J Med*, 367:2375, 2012.

Clinical Implications: This landmark study clearly establishes CABG as the superior revascularization modality compared to DES PCI in multivessel diabetic patients. This study certainly will be incorporated in the upcoming revascularization guidelines.

7. Appropriateness of coronary revascularization for patients without acute coronary syndromes. Hannan E, Cozzens K, Samadashvili Z, Walford G, Jacobs A, Holmes D Jr, Stamato N, Sharma S, Venditti F, Fergus I, King S 3rd. *J Am Coll Cardiol*, 59:1870, 2012.

Clinical Implications: This study reports the status of appropriateness use criteria (AUC) in determining the indications for PCI in stable CAD patients. It was reported that 14% of PCIs in NY State were inappropriate, while for MSH that figure was remarkably low at 3.4%. We need to be vigilant in ensuring that we perform PCI in the appropriately indicated patients.

8. Changes in Von Willebrand factor-cleaving protease (ADAMTS-13) in patients with aortic stenosis undergoing valve replacement or balloon valvuloplasty. Bander J, Elmariah S, Aledort L, Dlott J, Stelzer P, Halperin J, Kini A, Sharma S. *Thromb Haemost*, 86:93, 2012.

Clinical Implications: This study is first to identify that even BAV in severe AS patients correct various hematological abnormalities (such as reduced cleavage of VWF or VWF cleavage protease) and explains the mechanism of decrease in GI bleeding post-BAV and surgical valve replacement.

9. Increased expression of oxidation-specific epitopes and apoptosis are associated with haptoglobin genotype: Possible implications for plaque progression in human atherosclerosis. Purushothaman K, Purushothaman M, Levy A, Lento P, Evrard S, Kovacic J, Briley-Saebo K, Tsimikas S, Witztum J, Krishnan P, Kini A, Fayad Z, Fuster V, Sharma S, Moreno P. *J Am Coll Cardiol*, 60:112, 2012.

Clinical Implications: This mechanistic study takes another step toward solving the puzzle of plaque progression by implicating oxidation-specific epitopes in macrophage apoptosis.

10. Open versus endovascular stent graft repair of abdominal aortic aneurysms: A meta-analysis of randomized trials. Dangas G, O'Connor D, Firwana B, Brar S, Ellozy S, Vouyouka A, Arnold M, Kosmas C, Krishnan P, Wiley J, Suleman J, Olin J, Marin M, Faries P. *JACC Cardiovasc Interv*, 5:1071, 2012.

Clinical Implications: This meta-analysis of AAA treatment comparing open to endovascular repair highlighted the survival advantage of endovascular stent graft and hence could be recommended as the preferred treatment strategy.

Top 10 Key Clinical Trials

Among the 42 clinical research trials being conducted at the Mount Sinai Heart Cath Lab, below are the top 10 trials, which are likely to have a significant impact in the field of interventional cardiology.

Study Title	Study Details	Sponsor	Principal Investigator(s)	Target Enrollment and Study Sites	Current Status Enrollment at MSH
FREEDOM Trial	Randomized trial comparing CABG vs. PCI in diabetics with multivessel disease, to evaluate whether PCI with DES is more or less effective than the existing standard of care, CABG. Multicenter, two-arm, open label prospective randomized superiority trial with equal allocation of 3 years' duration.	National Heart, Lung and Blood Institute (NHLBI)	S. Sharma	2,058 (global)	Completed/71 subjects enrolled, 35 PCI / 36 CABG Results presented in AH/ 2012 and published in NEJM December 2012
Core Valve U.S. Pivotal Trial and Continued Access Study	U.S. pivotal clinical trial of patients with severe aortic stenosis who are high risk or extreme risk for cardiac surgery.	Medtronic, Inc.	S. Sharma D. Adams	1,350 (USA) 42 centers	Ongoing/84 subjects enrolled
COLOR REGISTRY	Chemometric Observations of Lipid Core Containing Plaques of Interest in Native Coronary Arteries Registry using LipiScan Coronary Imaging System.	InfraReDx, Inc.	A. Kini	2,000 (USA) 50 centers	Ongoing/350 subjects enrolled
TRYTON Side Branch Stent Trial	Comparison of TRYTON stent in the side branch with DES in main vessel vs. PTCA in side branch with DES in main vessel.	Tryton, Inc.	S. Sharma	700 (USA) 75 centers	Completed/47 subjects enrolled
EXPERT-CTO Trial	Evaluation of the XIENCE V coronary stent, performance and technique in chronic total occlusion. Evaluates success of HT PROGRESS and HT PILOT guidewires.	Abbott Vascular, Inc.	A. Kini	240 (USA) 40 centers	Completed/50 subjects enrolled

Study Title	Study Details	Sponsor	Principal Investigator(s)	Target Enrollment and Study Sites	Current Status/ Enrollment at MSH
LEVANT II Trial	Study of Lutonix Moxy Drug-Coated Balloon, catheter vs. standard PTA catheter in treatment of femoropopiteal arterial disease.	LUTONIX, Inc.	P. Krishnan	400 (USA) 184 centers	Ongoing/22 subjects enrolled
IN.PACT Trial	A randomized trial of the IN.PACT Admiral Drug-Eluting Balloon vs. standard percutaneous transluminal angioplasty (PTA) for the treatment of atherosclerotic lesions in the superficial femoral and/or proximal popliteal (SFA/PPA) arteries.	Medtronic, Inc.	P. Krishnan	450 (USA) 55 centers	Ongoing/20 subjects enrolled
SYMPLICITY Trial	A randomized trial to demonstrate the safety and effectiveness of catheter- based renal denervation in patients with resistant hypertension.	Medtronic, Inc.	G. Dangas P. Krishnan	635 (USA) 88 centers	Ongoing/16 subjects enrolled, 3 randomized
RenalGuard Trial	A study to evaluate the safety and efficiency of the RenalGuard System when compared with standard care in the prevention of contrast-induced nephropathy (CIN) in the catheterization laboratory.	PLC Medical Systems	G. Dangas	326 (USA) 20 centers	Ongoing/17 subjects enrolled
EXCEL Trial	A study to evaluate whether PCI compared to CABG in treatment of left main stenosis + other significant coronary lesions with the XIENCE V stent will result in noninferior or superior rates of the composite measure of all-cause mortality, MI or stroke at 3 years.	Abbott Vascular, Inc.	A. Kini	2,600 (global) 165 centers	Ongoing/22 subjects enrolled, 11 randomized

Full-Time Senior Faculty



Clinical Interests

Coronary Artery Disease Interventional Cardiology Valvular Intervention

Samin K. Sharma, MD, FSCAI, FACC

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Education and Training

MBBS: SMS 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 Medical Center, 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 150 articles, over 350 abstracts and 12 book chapters, and has been the editor of Cardiology Clinic's December 2006 and February 2010 issues. He is the founding editor of the newly launched Interventional Cardiology Clinic. 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, Daily News, Washington Post, New York Magazine, 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), 2003-2008 and 2012 Best Doctors of U.S. News & World Report, 2008-2012 Super Doctors, 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. Dr. Sharma 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) at Mount Sinai Hospital.

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Annapoorna S. Kini, MD, MRCP, FACC

Director Cardiac Cath Lab Professor of Medicine, Cardiology Director, Interventional Cardiology Fellowship

Education and Training

MBBS: Kasturba Medical College Mangalore, India Residency, Medicine/Cardiology: University of Wales Cardiology, United Kingdom Fellowship, Cardiology: Mount Sinai Medical Center, NY Fellowship, Interventional Cardiology: Mount Sinai Medical Center, NY

Dr. Annapoorna Kini was appointed director of the Cath Lab in 2011. Dr. 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 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 COLOR Registry, and the CANAR Trial. She started HAPPY (Heart Attack Prevention Program for You) in 2012. This program on preventive health care initiative takes place during the February Heart Month. The HAPPY Program is for all, focusing on risk factor modification with diet, exercise and yoga. In 2011, Dr. Kini received the "Rock Star of Science" award from the American Heart Association. She is the recipient of 2011 Dean's Award for Excellence in Clinical Medicine at The Mount Sinai Medical Center for unprecedented clinical skills. She has been listed as a New York Times Magazine Super Doctor from 2009-2012.

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Clinical Interests

Intravascular Imaging Interventional Cardiology: CTO Hypertrophic Cardiomyopathy



Clinical Interests

Coronary Artery Disease Interventional Cardiology Valvuloplasty

Pedro R. Moreno, MD, FACC

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Education and Training

MBBS: Universidad Javeriana, Bogota Residency, Internal Medicine: Brigham and Women's Hospital Fellowship, Cardiology: Massachusetts General Hospital Fellowship, Interventional Cardiology: Massachusetts General Hospital

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 antiproliferative drug-eluting stents used worldwide. His research using nearinfrared spectroscopy was pivotal in the development of the now-ubiguitous 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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Clinical Interests

Coronary Artery Disease Interventional Cardiology Radial Intervention

Michael C. Kim, MD, FACC

Assistant Professor of Medicine, Cardiology Director, Coronary Care Unit Assistant Director, Cardiac Cath Lab

Education and Training

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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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MBBS: Rajah Muthiah Medical College, India Residency, Internal Medicine: St. Vincent's Medical Center of Richmond Fellowship, Cardiology: Ochsner Clinic Foundation Fellowship, Interventional Cardiology: Mount Sinai Medical Center, NY 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 the 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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George Dangas, MD, PhD, FACC, FSCAI

Professor of Medicine, Cardiology Director Cardiovascular Innovation

Education and Training

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

Dr. George Dangas performs a wide spectrum of complex cardiovascular interventional procedures annually to treat coronary and valvular heart disease, aortic, carotid and peripheral arterial disease as well as specialized treatment for resistant 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.



Clinical Interests

Peripheral Artery Disease Interventional Cardiology Endovascular Intervention



Clinical Interests

Clinical Cardiology Interventional Cardiology Endovascular Intervention



Clinical Interests

Restenosis Prevention Advanced Cardiac Treatment Kidney Injury After Contrast

Roxana Mehran, MD, FACC, FACP, FCCP, FESC, FAHA, FSCAI

Professor of Medicine and Health Policy Director of Interventional Cardiovascular Research and Clinical Trials

Education and Training

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

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 codirector of the annual Transcatheter Cardiovascular Therapeutics (TCT) conference for the last 15 years. Dr. Mehran is a member of the editorial board of multiple peerreviewed 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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Clinical Interests

Cardiac Catheterization Cardiac Transplantation Heart Failure

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Education and Training

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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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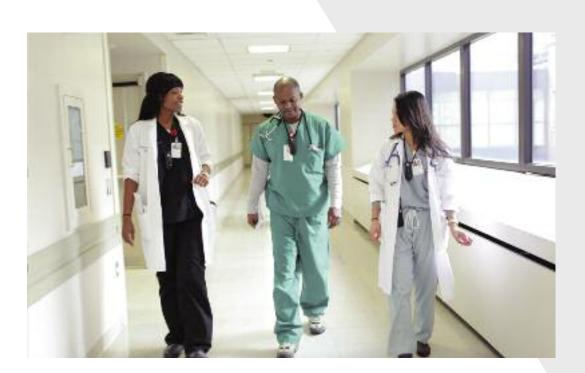
Dr. Barry Love is director of the congenital cardiac catheterization laboratory at Mount Sinai Heart. Dr. Love holds a joint appointment in both the department of Pediatrics and the Department of Medicine and is one of only a few physicians who performs interventional procedures on patients with congenital 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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Clinical Interests

Pediatric Catheterization and Intervention Adult Congenital Heart Disease



Full-Time Affiliate Faculty







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Master Teacher



Mazullah Kamran, MD

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MD: Universidad Autonoma De Santo Domingo, Santo Domingo Residency, Internal Medicine: Elmhurst Hospital, NY Fellowship, Cardiology: Brooklyn Hospital, NY Fellowship, Cardiac Catheterization, Nuclear Cardiology: Lenox Hill Hospital, NY **Clinical Interests:** Clinical Cardiology, Cardiac Catheterization, Coronary Interventions, Nuclear Cardiology **Phone: 212-439-6000 E-mail: falcardiology@gmail.com**







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Lynne Glasser, MD Assistant Professor of 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**

Asim Hameedi, MD

Clinical Instructor of Medicine, Cardiology Education and Training MD: SUNY Downstate Health Science Center, NY Residency: Albert Einstein College of Medicine/ Montefiore Medical Center Fellowship, Cardiology: SUNY Downstate Health Science Center, NY Fellowship, Interventional Cardiology: SUNY Downstate Health Science Center, NY Phone: 718-465-3200 E-mail: citimedical@aol.com

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Sidharth Yadav, DO

Assistant Clinical Professor of Medicine Education and Training DO: New York College of Osteopathic Med

DO: New York College of Osteopathic Medicine, Old Westbury, NY Residency: Saint Vincent Catholic Medical Center, New York, NY Fellowship, Cardiology: Saint Vincent Catholic Medical Center, New York, NY Fellowship, Interventional Cardiology: Lankenau Medical Center, Wynnewood, PA **Clinical Interests:** Cardiac Catheterization, Coronary Intervention, Endovascular Intervention **Phone: 718-323-2229 Email: syadav@nyit.edu**

Beth Oliver, RN



Vice President of Clinical Operations, Mount Sinai Heart
Education and Training
BS, Nursing: University of Massachusetts, Boston
Nurse Practitioner Certification: Columbia University
DNP: Case Western University
Beth Oliver is responsible for the executive leadership of the clinical services within
Mount Sinai Heart. Beth is a past recipient of the Ellen Fuller Award of Excellence in
Nursing Leadership as well as the AHA Heart Hero Award. She is a member of Sigma
Theta Tau, the National Nursing Honor Society; the American Organization of Nurse
Executives (AONE) as well as the Board of Directors of the American Heart Association.
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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 and effectively manages a unit with complex staff of more than 167 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 and 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.

Phone: 212-241-1835

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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

Cath Lab Nurse Practitioner/Physician Assistant (PA) Team

Mount Sinai's dedicated staff of nurse practitioners and physician assistants 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



Melissa Mattimore



Kevin Williams



Gloria Manzanilla



Leticia Jakasal





Rheoneil Lascano



Suzette Chan



Pitakmongkolkul





Tanya Sullivan





Haydee Garcia



Tia Coleman



Kristelle Pulido



Dominique Sicile



Isaac Hammond, PA



Sandie Romain

Interventional Cardiology Fellows

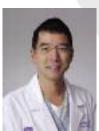
Mount Sinai Heart's interventional cardiology fellowship program is the largest in the country, educating the next generation of clinical cardiology and interventional cardiology specialists. This well-regarded program, which combines academic and hands-on experience, has graduated physicians who are serving as noted leaders in community and academic medical centers.



Anthony Patrello, MD



Bakhtiar Ali, MD



Bernie Changsiri, MD



Jennifer Yu, MD



Laxman Prajapat, MD



Michael Broukhim, MD



Rajeev Narayan, MD



Reji Pappy, MD



Rohit Bhuriya, MD



Thomas Kawano, MD



Interventional Database Team

(Left to Right) Swapna Sayeneni, Swathi Roy, Birju Narechania, Delenia Gulle, Arjun Bhat, Roja Thapi, Elena Ramos

Interventional Research Team

(Left to Right) Arthur Tarricone, Mindy Lopez, Carolina Capunay, Ecaterina Cristea, Kleanthis Theodoropolous, Theresa Franklin-Bond, Asif Adam, Miguel Vasquez, Kameswari Vallabhajosyula





Supporting Staff

(From Left to Right starting on the bottom) Pearl Tongson, Jackie Nordstrom, Maria Directo, Kelly Worell, StacyAnn Reid, Shulandia Avila, Debra Bradley, Era Zuberko

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.



Mount Sinai Cath Lab Partners & Affiliates







Bon Secours Charity Health System

Good Samaritan Hospital Suffern, NY



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.

Cardiology Unlimited, Eliscer Guzman, MD, PC

Broadway Cardiopulmonary, PC

Astoria Cardiology, PC

Hemant Patel, MD, PC

Levit Medical Center, PC, 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, PC

Park Avenue Family Practice, LLC, James Sayegh, MD

Riverside Medical Group, Sudhakar Mettu, MD, & Associates

Manhattan Medical Group, Shuja Qadir, MD

Medicine from the Heart, PC, Gary Spektor, MD, PC

Mount Sinai of Staten Island, Seshadri Das, MD

Clinica Modelo, Washington Heights, PC

Westchester Family Practice, PC, Iyad Annabi, MD

Westchester Health Associates, George Berk, MD, & Associates

Midland Avenue Family Practice, PC, Steven Francescone, MD

Manuel Velasquez, MD, PC

Tracy Townes, MD, Chaula Patel, MD, PC

Arshad Anwar, MD, PC

Cardiology PC, Saeed Siddiqui, MD

Viera Henteck, MD, PC

We Care Health & Medical Services, PC, Carlos Diggs, MD

Heights Medical Care, PC, Larry Neuman, MD

DOC Medical Office of Yonkers & Bronx, Rajeev Sindhwani, MD

Hamid and Aslam Medical Group, Inc.

JAMA Group, LLC, PC, Javed & Daniel Yadegar, MD

Bronxville Internal Medicine, PC, Mazan Rabadi, MD

Prime Care Medical Group, Jamaica, PC

Prime Care Medical of Brighton, PC, Iffat Sadique, MD

Qazi Kamal Haider, MD, PC

Gondal Medical Care, PC, Imtiaz Ahmad, MD

Multi Medical Care, PC, Ferdausi Hassan, MD

Knickerbocker Medical Care, PC, Syed Shahid Hassan, MD

Northern Heart Specialists, PC

Seventh Avenue Medical, PC, Michael Jones, MD

Panagiotis Pagonis, MD, PC

Juhno Lee, MD, PC

786 Medical PC, Rafiq Chaudhry, MD

North Broadway Internal Medicine, Ranjan Cain, MD

Northern Heart Specialists PC, Choudry MD, Maddipitti Medical Associates East, William Boxer, MD

Lawrence Neshiwat, MD, PC

Kernilde Jean Jerome, MD, PC

South Island Medical Associates, PC, Lalendra Sinha MD

Stephen Esposito, MD, PC

Todd McNiff, MD, P.

United MedServ, Inc, PC, Mohammad M. Billah, MD

Ro K. Young, MD, PC

Heart & Health PLLC, David Kavesteen, MD

Grand Family Immediate Care, Albert Benchabbat, MD

Ginny and Paul Leva, MDs, PC

Complete Medical of NY, PC, Eric Goldberg, MD

Faisal Waseem MD, PC

Amsterdam Medical Practice, Eduardo Pignanelli, MD

AJU Medical Center, William Shin, MD

AM Evaluation Services, LLC, Richard Biera, MD

Heights Physicians Group, PC, Jorge Alvarado-Rivera, MD

Howard Orkin, MD, PC

Internal Medicine, PLLC, Mark Sandigursky, MD

Advanced Medical, Arshad Anwar, MD

Pushpinder Singh Medical Practice, Inc., PC, Pushpinder Singh, MD

Academy Medical Care, PC, Ramon Tallaj, MD



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NEW 4-Day Symposium Format

NURSE / TECHNOLOGIST SYMPOSIUM | Tuesday, June 11th

ENDOVASCULAR INTERVENTION | Iliac, Femoral, Renal, Carotid | Wednesday, June 12th

COMPLEX CORONARY INTERVENTION Unprotected Left Main, Calcified, Bifurcation, and Chronic Total Occlusion Thursday, June 13th

STRUCTURAL HEART / CORONARY INTERVENTION | TAVR, Valvuoplasty, Septal Ablation, PFO/ASD Closure | Friday, June 14th



Highlights

- Complex High-Risk Coronary Cases
- Unprotected Left Main
- Chronic Total Occlusion
- Distal Protection Devices
- Alcohol Septal Ablation
- Aortic and Mitral Valvuloplasty
- Percutaneous Valve Replacement
- Peripheral, Endovascular and Carotid Stenting PFO/ASD Closure



Samin K. Sharma, MD, FACC, FSCAI

sium Co-Directors Pedro Moreno, MD, FACC Roxana Mehran, MD, FACC, FSCAI Robert Pyo, MD Joseph M. Sweeny, 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

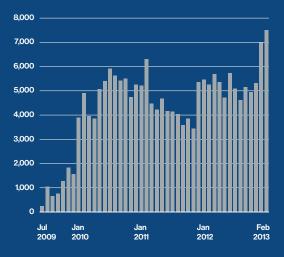
Target Audience

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

2013 Web Conference Schedule

8:00 TO 9:00 AM May 15, 2013 June 18, 2013 July 16, 2013 August 20, 2013 September 17, 2013 October 15, 2013 November 19, 2013 December 17, 2013

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The mission of the Cardiac Catheterization Lab at Mount Sinai Heart is: To improve outcomes and experience of interventional patients by innovations, research, clinical and personalized care.