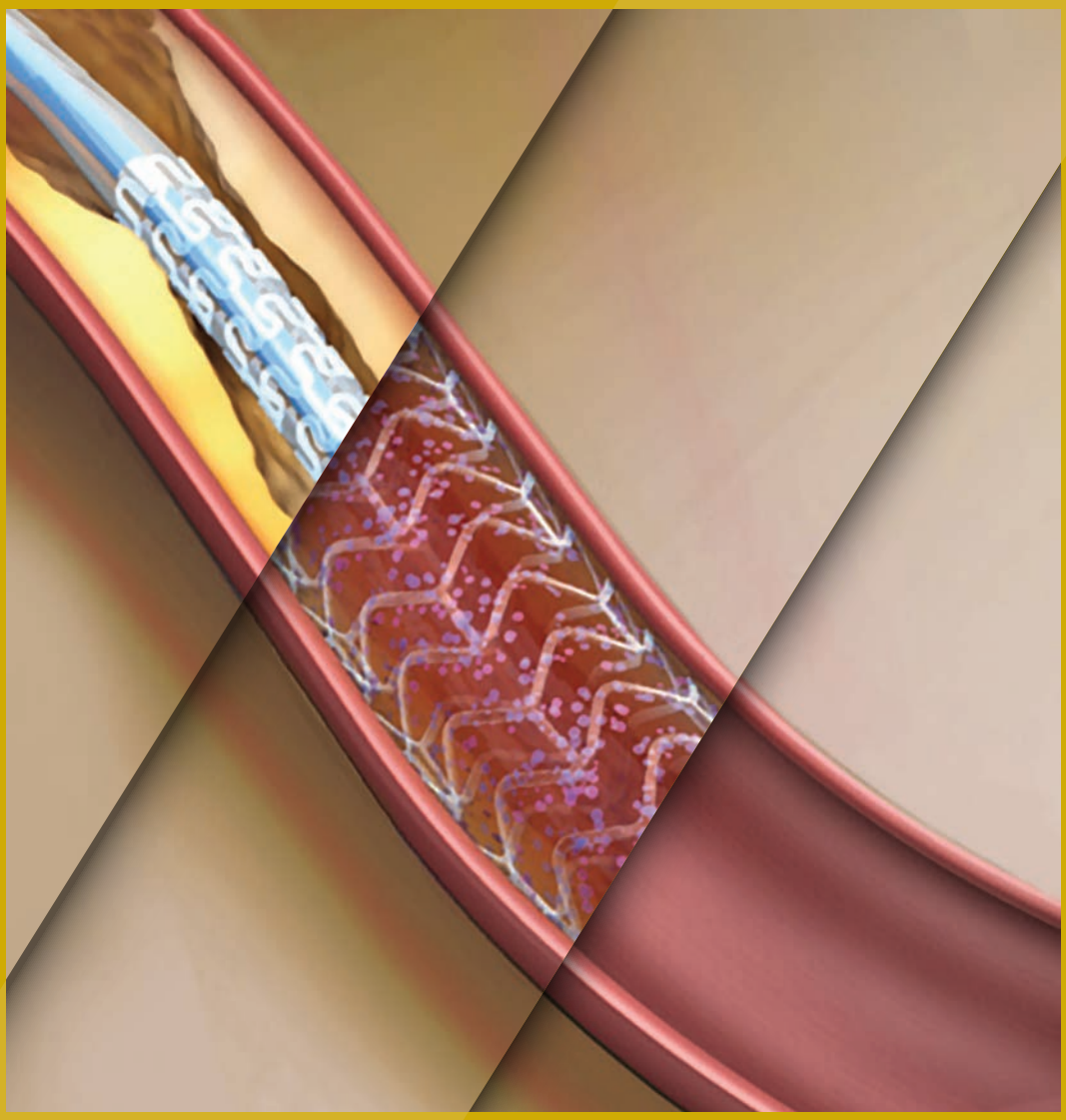
CARDIAC CATHETERIZATION LABORATORY

2014 CLINICAL OUTCOMES REPORT



PATIENT-CENTERED CARDIAC EXCELLENCE

Mount Sinai *Heart*

A Message From Dr. Sharma & Dr. Kini

Dr. Samin K. Sharma

Director, Clinical & Interventional Cardiology
President, Mount Sinai Heart Network
Dean, International Clinical Affiliations
Zena & Michael A. Wiener Professor of Medicine

Dr. Annapoorna S. Kini

Director, Cardiac Catheterization Laboratory
Director, Interventional Cardiology Fellowship Program

Dear Colleague:

We of the Cardiac Catheterization Laboratory at The Mount Sinai Hospital are proud to present our patient-centered 2013 outcomes report, a comprehensive overview of the work being done at the nation's largest and finest cardiac catheterization laboratory. Public reporting of quality outcomes and patient safety data is increasingly being mandated for transparency by various organizations and stakeholders. In this issue, we report our performance metrics and compare them to regional and national standards, with the sole purpose of providing the best care to our patients.

Technical and technological advances in the field of percutaneous coronary intervention (PCI) have resulted in a relentless drive for procedural excellence. Our outcome data over the last five years supports how we at Mount Sinai have *perfected the art of PCI.*

The management of coronary artery disease (CAD) patients is rapidly changing, with medical therapy playing a major role in the routine management of CAD patients. There has been an increase in percutaneous coronary intervention in patients with moderate to severe CAD as well as in patients with acute coronary symptoms. Patients with extensive diabetes have had an increase in coronary artery bypass surgery (CABG) to improve long-term survival. Overall rates of percutaneous and surgical revascularization have decreased due to aggressive and optimal medical management of CAD patients. Despite the increase of complex cases, we have observed an overall decline in complications because of our expertise, teamwork and dedication in treating each patient as an individual. We are committed to the universal use of innovative and evidence-based standardized medical protocols, which has contributed to our extraordinary success. It is not unusual for patients who have been deemed "inoperable for advanced extensive cardiac disease" to come to us, be treated successfully, and go home with smiles on their faces.

In order to remain at the top, we will continue to employ cutting-edge technology and techniques that are now the hallmarks of our success. In this issue we will provide details of several innovations that have contributed to our national and international recognition and highlight these innovations through stories of grateful patients. Our goal for 2014 is to rise to eminence from excellence by innovation and well-organized comprehensive care in the field of interventional cardiology.

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Clinical Outcomes 2014

Welcome

Kenneth L. Davis, MD

President and Chief Executive Officer,
Mount Sinai Health System

Dennis S. Charney, MD

Anne and Joel Ehrenkranz Dean
Icahn School of Medicine at Mount Sinai

David Reich, MD

President and Chief Operating Officer,
The Mount Sinai Hospital

The Mount Sinai Cardiac Catheterization Laboratory has demonstrated many years of excellent quality and outcomes. The safety record is impressive, especially in light of the growing numbers of complex interventions for coronary, valvular, congenital and electrophysiological diseases. The safety record in outcomes registry results and the strong research output speak to the excellence of the clinical and research teams. It is therefore a pleasure to introduce this sixth edition of the *Cardiac Catheterization Laboratory Clinical Outcomes Report.*

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

We hope you find this sixth edition of the *Cardiac Catheterization Laboratory Clinical Outcomes Report* to be informative.

A Message from Valentin Fuster, MD, PhD, MACC

Valentin Fuster, MD, PhD, MACC

Physician-in-Chief,

The Mount Sinai Hospital

Director, Mount Sinai Heart

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

Richard Gorlin, MD, Heart Research Foundation Professor of Cardiology

The field of cardiovascular medicine continues its steady advance, and we at Mount Sinai Heart are proud to be part of the charge. Now in its eighth 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 with extraordinary clinical skills — one of the patients profiled in this book was told by her referring physician that "Sharma could put a stent in a stone" — and he demands that his team of interventionalists and support staff measure up to the same high standards. Another of his remarkable gifts is his ability to form a bond of trust with the patients who put their lives in his hands. His compassion is honest and true.

Day and night, patients are arriving at the Cardiac Catheterization Laboratory, from every borough in the city and from the entire tristate area. They may have an elective procedure scheduled, or they may be in the throes of a myocardial infarction. Depending on the number and severity of the cases, the atmosphere in the Cath Lab can be very intense, but every member of the team is trained calmly to deliver care of uncompromising quality.

The Innovations section of this report might be called its heart: it describes in detail both intriguing avenues of investigation and blockbuster breakthroughs, which may be the outcome of clinical trials (for which The Mount Sinai Hospital is often a participating site). Among the many topics discussed in that section are the optimal treatment for stable ischemic heart disease; updated criteria for revascularization choices in patients and also specifically in diabetic patients with coronary artery disease; the new generation of self-expanding stents; the bioabsorbable stent; the temporary ventricular assist device; a new, smaller duct occluder to treat patent ductus arteriosus; efforts to arrive at treatment strategies that achieve the optimal balance between bleeding risk and ischemic risk in patients who have undergone percutaneous coronary intervention (PCI); the identification of lesions susceptible to plaque rupture and thrombosis; and of course the latest data on transcatheter aortic valve replacement (TAVR).

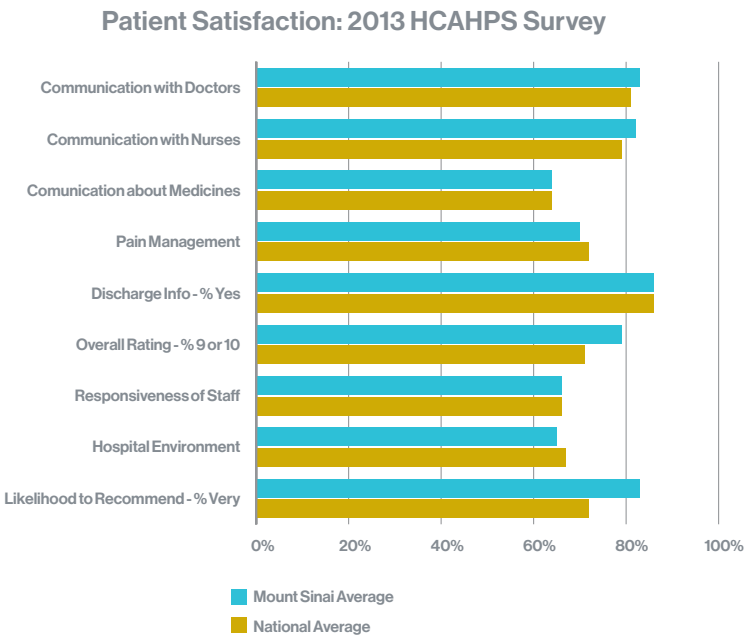
Again this year we offer "testimonials" from grateful patients. They tell us their stories eagerly; we could fill several volumes with patient testimonials alone. Over and over again, they express their trust in their doctors, their gratitude, their joy and delight at being made well. And making people well is at the heart of what we do.

The Cardiac Catheterization Lab

An Overview of Services and Outcomes

Richard Nixon once said, *"You must never be satisfied with success and you should never be discouraged by failure."* These two essential concepts of life are the guiding principles of the success of our Cath Lab.

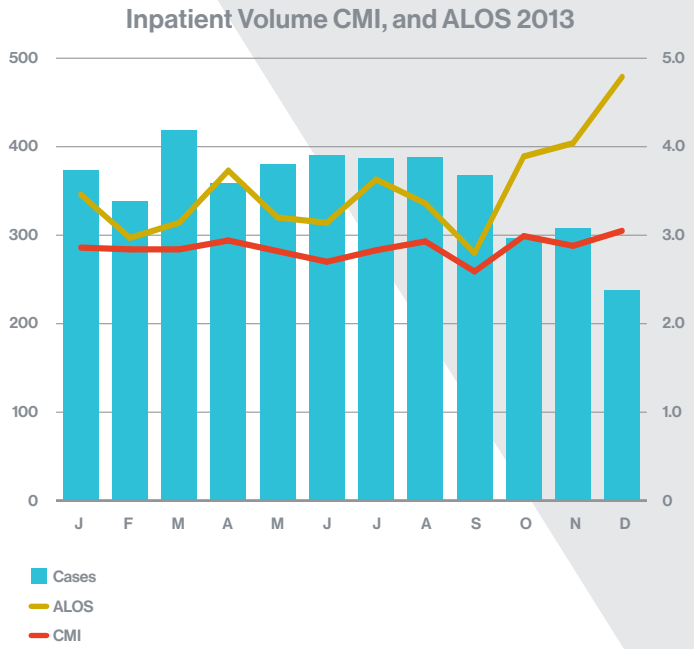
Mount Sinai Heart, encompassing clinicians, scientists, nurses and associated caregivers under the leadership of visionary director Valentin Fuster, MD, PhD, has emerged as a premier cardiovascular center. Our patients benefit from a complete range of clinical services as well as the latest clinical trials and research to treat cardiovascular ailments. The extraordinary care we offer has resulted in our ascent nationally from 50th in 2007 to 13th in 2013 (*U.S. News & World Report* 2013).



The Cardiac Catheterization Laboratory at Mount Sinai Heart is the one of the safest and busiest interventional catheterization laboratories in the United States. Our Cardiac Cath Lab, consisting of seven 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). In addition, we have access to the hybrid OR suite to perform TAVR that requires direct aortic access.

Efficiently managing the growing cath volume and the complexity of invasive cases is demanding on our physical infrastructure and our Cath Lab staff. The number of both medical and nonmedical staff has grown tremendously to over 160, to serve the ultimate goal of delivering safe, appropriate and excellent care.

Presently there are four full-time staff senior attendings, 12 full-time staff affiliate attendings, 11 part-time/voluntary staff interventional attendings, four voluntary cath attendings, four congestive heart failure (CHF)/transplant attendings, one pediatric cath attending, nine interventional fellows and 17 nurse practitioners/physician assistants. Each member of the 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.



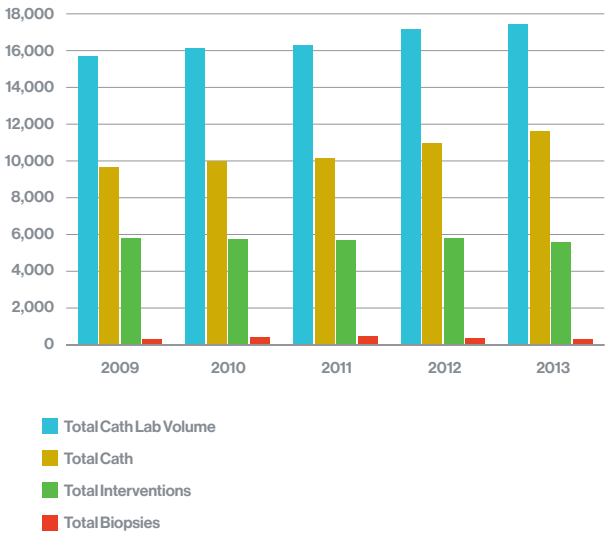
One very important aspect of patient satisfaction is making the in-hospital stay as short as possible. With this in mind, approximately 58 percent of our elective interventional patients are safely discharged on the day of the procedure (Ambulatory percutaneous coronary intervention (PCI)) following an established ambulatory discharge protocol. Others with more complex interventions, comorbid conditions and higher acuity are admitted for observation; the majority are discharged home next day. The 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, 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.

Our Cath Lab takes pride in educating future clinical cardiology and Interventional Cardiology Specialists by establishing a rigorous academic and hands-on training program for the largest interventional fellowship program in the U.S. At right are the 2013-14 interventional fellows (seven ACGME and five non-ACGME) with program director Annapoorna Kini, MD.

Growth and Trends in Cardiac Cath Lab Volume and Procedures



Interventional Volume and Major Complications (MC)

ASA = 18

Comparative Quality Parameters of Interventional Procedures

Growth and Trends in Cardiac Catheterization Laboratory Volume and Procedures

The volume of diagnostic cath and interventional procedures at the Mount Sinai Cardiac Catheterization Laboratory declined approximately 4 percent from 2012 to 2013; largely due to a 6 percent decline in percutaneous coronary intervention (PCI) cases, an 11 percent increase in valvular interventions, and unchanged endovascular interventions.

Total percutaneous interventions encompass percutaneous coronary interventions (PCI for coronary artery disease); endovascular interventions (for diseased limb, cerebral, or renal arteries); valvuloplasties (for stenosed aortic or mitral valves); transcatheter aortic valve replacement/implantation (TAVR/TAVI for stenosed aortic valves); alcohol septal ablation (for hypertrophic obstructive cardiomyopathy or HOCM); and interventions for other structural heart diseases, such as ASD and PFO closure. In 2013, despite a small increase in total diagnostic procedures, there was a decline in total interventions to 5,549 from 5,806 in 2012: 4,492 PCI, 790 endovascular interventions, 133 balloon aortic valvuloplasties, 12 balloon mitral valvuloplasties, 104 TAVR procedures and 18 alcohol septal ablations (ASA). In mid-2012, we started performing intravascular brachytherapy (IVBT) for recurrent in-stent restenosis (two or more times) after drug-eluting stents. Our cumulative experience now includes more than 130 successful IVBT cases with a restenosis rate of about 20 percent compared to 60 percent without IVBT. Our Cath Lab was the first in the world to perform orbital atherectomy (OA), a newly approved device to treat severe calcified coronary lesions. Carotid stenting is now routinely performed by our interventionalists in conjunction with vascular surgeons; 38 cases were successfully performed in 2013 without any major complications. The majority of PCI cases (95 percent) are done using stents [(drug-eluting stents (DES) in 94 percent; bare metal stents (BMS) in 6 percent)] with an adjunct 10 percent using rotational/orbital atherectomy, another 2 percent applying thrombectomy/embolic protection devices, and the remaining 5 percent percutaneous transluminal coronary angioplasty (PTCA) only.

The observed changes and decline in the interventional volume is consistent with the national trend; a decrease in PCI volume and growth in endovascular and valvular procedures, especially TAVR. Thanks to our established reputation for handling complex coronary and valvular cases with success and safety, approximately one-third of our interventional patients are referred to us by physicians (internists, cardiologists and interventionalists) outside of our hospital network.

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

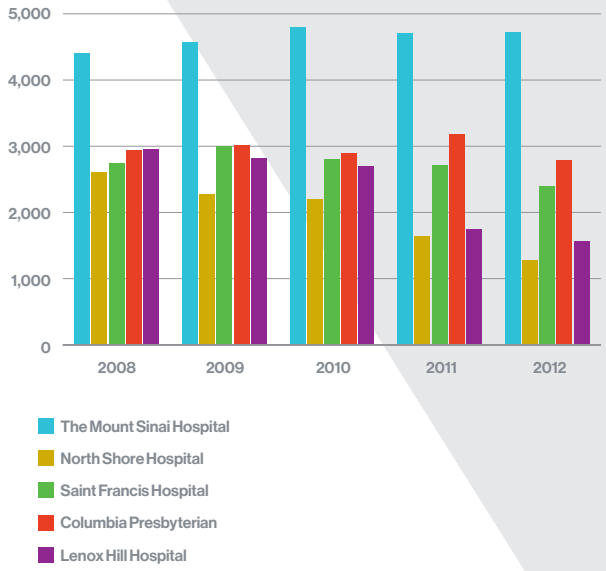
The chart at right shows The Mount Sinai Hospital's Cardiac Catheterization Laboratory volume for all types of interventions over the past five years. Our lab rose to the top position among New York State hospitals in 2005 and has continued to deliver interventional care to the greatest number of patients compared to other New York State hospitals for the last eight years, according to New York State Department of Health statistics.

Interventional Outcomes and Temporal Complication Trends

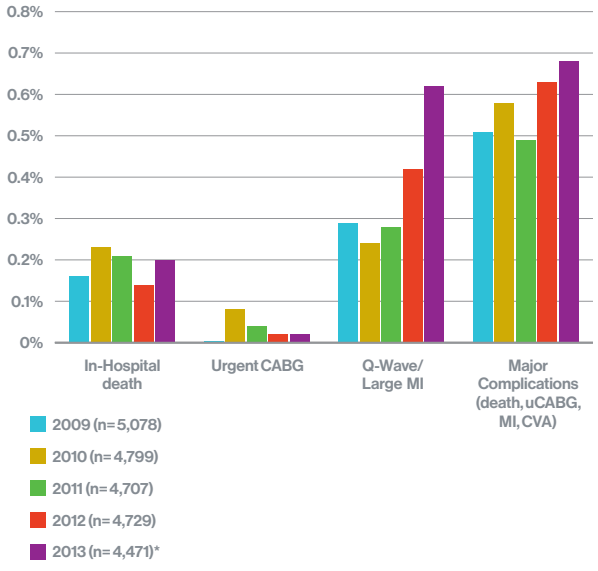
The system of established standard protocols, rigorous attention to minute detail and a strong sense of teamwork have helped us to achieve some of the best interventional outcomes in the country. We continue to improve our outcomes each year, with unprecedented extremely low procedural complications in 2013; combined major complications of death, large MI, urgent CABG and CVA cases under 0.7 percent.

This remarkably low complication rate has been achieved despite the high complexity of cases and comorbid medical conditions of patients being treated in the Cath Lab. Reports of risk-adjusted PCI mortality over the last 15 years by the NYS Department of Health have consistently placed the Mount Sinai Heart Cath Lab among the lowest for in-hospital and 30-day risk-adjusted mortality. The most recent New York State DOH report of 30-day risk-adjusted mortality rate (RAMR) for year 2011 has shown our incidence of 0.79 percent for all cases, 0.55 percent for elective cases and 2.35 percent for emergency PCI cases; which is about 30 percent lower than the statewide average. In the latest 2009-2011 PCI report, we are one of two centers to receive a double-star (**), which denotes

NYS DOH-Reported PCI Volumes for the Past Five Years



Temporal Trends in Complications of PCI at MSH



*New post procedure MI definition = CK-MB >5x

NYS-DOH Report of PCI 2009-2011

PCI Statistics 2009-2011	# Cases	All Cases	Non-Emergency Cases	Emergency Cases
1. The Mount Sinai Hospital	**14,525**	**0.71****	**0.44****	**2.35**
2. Columbia Presbyterian Hosp.	8,779	0.80	0.53	2.13
3. Saint Francis Hospital	8,698	0.74	0.44	2.75
4. Lenox Hill Hospital	7,501	0.69	0.37**	3.12
5. Saint Joseph's Hospital	6,657	0.95	0.73	2.65
6. LIJ Medical Center	5,820	0.72	0.52	1.86
7. North Shore University Hospital	5,450	0.60**	0.52	1.26**
8. Rochester General Hospital	5,326	1.16	0.72	3.78
9. Stony Brook Hospital	5,091	1.02	0.57	3.57
10. Beth Israel Medical Center	4,941	0.78	0.41	3.41
NYS Total	**158,289**	**0.91**	**0.57**	**3.02**

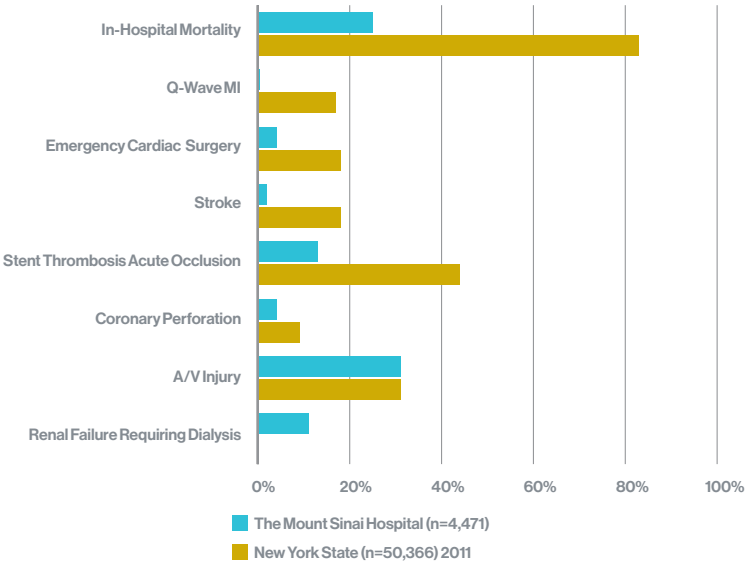
www.nyhealth.gov **Risk Adjusted Mortality Rate (RAMR) significantly lower than statewide rate

NYS-DOH 30-day RAMR for PCI at MSH for Last Five Reports

Years/ # cases	All cases RAMR %	Non-Emergency cases RAMR %	Emergency cases RAMR %	**Interventionalist at MSH
2009-2011/ 14525	0.71**	0.44**	2.35	Dr. Kini
2008-2010/ 14414	0.64**	0.41**	2.55	Dr. Moreno
2007-2009/ 13993	0.67**	0.45**	2.21	---
2006-2008/ 13742	0.63**	0.45**	1.78**	Dr. Sharma
2005-2007/ 13030	0.64**	0.49	1.62**	Dr. Kini Dr. Sharma

www.nyhealth.gov **Risk Adjusted Mortality Rate (RAMR) significantly lower than statewide rate

NYS-Reported Major Complications Following PCI 2013



significantly lower RAMR than the statewide average. Over the past 15 years of New York State Department of Health reporting, the double star has been awarded to Mount Sinai each year, either in the PCI category or to a physician. Receiving the double star every year in two PCI categories is unequaled by any PCI center in New York State.

This lower 30-day risk-adjusted mortality can be attributed in large part to the experience and high procedural volume of the senior full-time interventionalists, who aggregately perform more than 4,000 cases per year. Dr. Kini and Dr. Sharma in 2007, Dr. Sharma in 2008, Dr. Moreno in 2010 and Dr. Kini in 2011 were awarded the double star by NY State, denoting significantly lower 30-day risk-adjusted mortality among approximately 600 interventionalists practicing in the state.

These low complication rates, credited to a uniform protocol across all staff, are all the more remarkable when one considers 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 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 The Mount Sinai Hospital Interventional Outcomes with Others

The graphs at right show the superior outcomes of PCI patients at The Mount Sinai Hospital in comparison to New York State and national ACC-NCDR hospitals.

Other Quality Interventional Parameters of The Mount Sinai Hospital

Appropriateness of PCI for Stable CAD

Recently, 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 by federal agencies or insurance companies. At Mount Sinai we established the evidenced-based system protocol of proper evaluation of CAD patients before scheduling them for catheterization and possible intervention; this combined with rigorous application of the appropriate use criteria (AUC) of the American College of Cardiology (ACC) has yielded one of the lowest rates of inappropriate PCI for stable CAD in the nation.

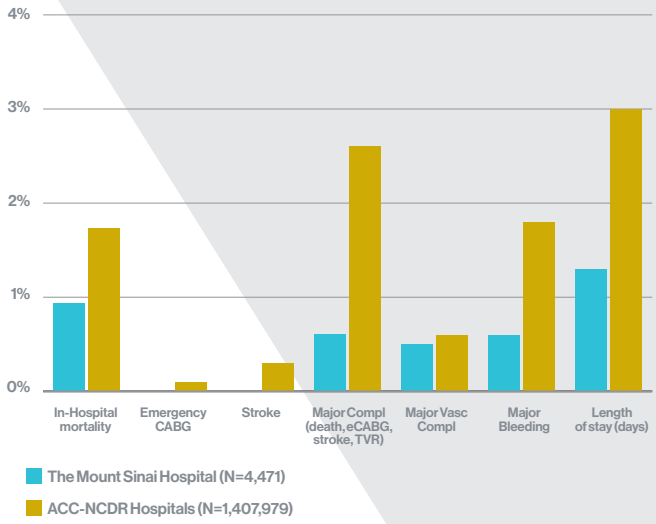
Primary PCI < 90 Minutes

PCI performed in less than 90 minutes from arrival at the hospital (door-to-balloon time) is an important Centers for Medicare and Medicaid Services (CMS) quality parameter and is publicly reported for all hospitals. The proportion of STEMI patients at The Mount Sinai Hospital undergoing PCI in less than 90 minutes was 96 percent in 2013.

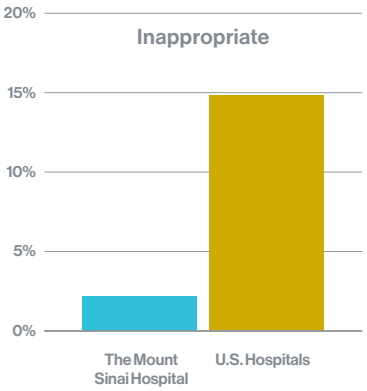
In-Hospital Mortality of STEMI Patients

According to the ACC/NCDR Report of 2013, risk-adjusted mortality of STEMI patients at Mount Sinai Heart was less than one-third that of other comparable U.S. hospitals.

PCI Complications: MSH vs. ACC-NCDR Hospitals 2013



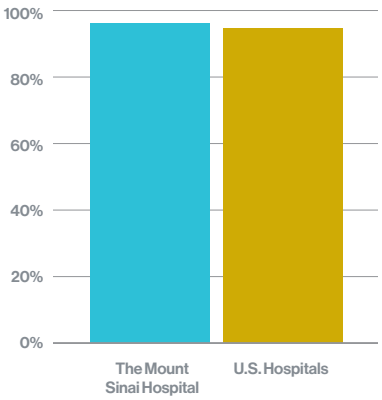
Appropriateness of PCI



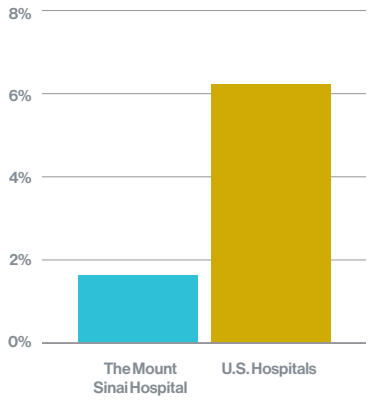
AUC Metrics at MSH compared to U.S.; ACC-NCDR (n=1,400 hospitals; >1.4 million PCIs) for 2013

Proportion of non-ACS PCI procedures at MSH versus other U.S. hospitals classified as inappropriate

Proportions of STEMI Patients Receiving PCI <90 minutes in 2013



In-Hospital Mortality for STEMI in 2013 (Risk-Adjusted)



Innovations

Samin K. Sharma, MD, FSCAI, FACC

To view a complex case of balloon aortic valvuloplasty, orbital atherectomy and DES of left main and LAD, scan the QR code below or visit http://www.cccsymposium.org/2013-livecase06.html

Updated Criteria for Revascularization Choices in Patients with Coronary Artery Disease

In the last few years, there has been increasing consensus about the treatment of CAD patients; maximal medical therapy for mild to moderate disease, percutaneous coronary intervention (PCI) in moderate to severe disease and CABG preferentially in severe advanced multivessel disease and diabetic patients.

The SYNTAX (SYNergy Between Percutaneous Coronary Intervention with TAXus and Cardiac Surgery) Trial was conducted at 85 sites in 17 countries, enrolling 1,800 patients with left main or three-vessel coronary artery disease or three-vessel disease. It sought to establish a grading tool, known as a SYNTAX score, for determining the complexity of coronary artery disease and helping interventionalists, surgeons and patients choose between percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) surgery. Patients were randomly assigned to CABG (n = 897) or PCI (n = 903).

PATIENT: Diane Vitalis, 69-year-old woman

DIAGNOSIS: Refractory angina from extensive coronary atherosclerosis and in-stent restenosis and occluded bypass grafts.

TREATMENT: Successful intervention of LAD-proximal and -mid using rotational atherectomy and PTCA and second-stage, successful interventional of RCA using rotational atherectomy and two drug-eluting stents.

"I feel fine now, better than I've felt in many years"

"My adventure with my heart began in 1998. I was having chest pains, and my internist performed an EKG and sent me to a cardiologist, Dr. George Berk. He ordered a nuclear stress test, which showed a blockage, and he advised me to get to the hospital immediately. I was apprehensive, and I told Dr. Berk I needed a sign from God. The next words out of his mouth were, 'If you were my sister I would carry you right into the ER.' That was the confirmation I needed; my big brother, Nick, who had suffered a heart attack and died in 1968, had once carried me into the ER when I fell and hit my head in a roller skating accident.

"So I consented, and I was taken to a Westchester hospital where I received a bare metal stent. The doctor who performed the procedure told me my left anterior descending artery had been 99.99 percent blocked. But that was not the end of my adventure!

"Over the next decade, I had more noncoated stents implanted, and I continued to suffer from angina, which was often quite painful and sustained. I moved to Florida, and in 2008 I had a major heart attack and underwent quadruple bypass. Within two years, two of those grafts had failed, and I was having debilitating heart spasms every day. I said to Dr. Berk, 'There must be someone who can help me,' and he suggested Dr. Sharma. He told me, 'Dr. Sharma could put a stent in a rock,' and I said, 'That is the doctor I want.'

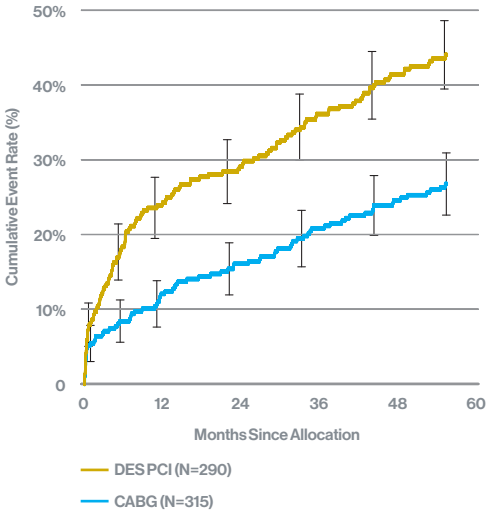
"He sent all my records to Mount Sinai, and Dr. Sharma's NP, Vivian, called me within a week to say, 'We have scheduled you for a procedure.' No further discussion. Dr. Sharma placed three drug-eluting stents in the native arteries on the right side of my heart, and seven weeks later he cleared the three native arteries on the left side using the Rotablator, which breaks up calcified lesions.

"I feel fine now, better than I've felt in many years, and I know that Dr. Sharma was an answer to my prayers. God gave him golden hands, and with those hands he gave me hope for the future. I will always be grateful."

Five-year follow-up data from the SYNTAX Trial, reported late in 2012, revealed that intermediate to high syntax score (more than 22) patients in the CABG arm were observed 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. This observation held true for both diabetics and non-diabetics.

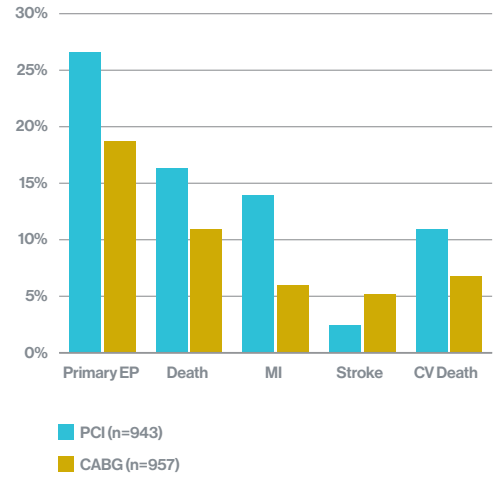
The conclusion was that CABG should remain the standard of care for those patients whose scores were in the intermediate range and above and were not at high risk for undergoing cardiac surgery; as a result CABG rates for advanced CAD have increased at many hospitals, including Mount Sinai. At Mount Sinai Heart, we have been incorporating SYNTAX score in the stratification of patients with advanced coronary artery disease (CAD) for choice of revascularization modality.

SYNTAX Trial: MACCE to 5 Years in High SYNTAX Score Tercile (>32)



	CABG	PCI	P value
Death	11.4%	19.2%	0.005
CVA	3.7%	3.5%	0.80
MI	3.9%	10.1%	0.004
Death, CVA or MI	17.1%	26.1%	0.007
TVR	12.1%	30.9%	<0.001

FREEDOM Trial: Outcomes at 5 Years after Randomization in Diabetic Patients



Another relevant study was the FREEDOM (Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease) Trial, 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.

The five-year FREEDOM data showed that the primary outcome — a composite of all-cause mortality, myocardial infarction (MI) or 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, and 10.9 percent vs. 16.3 percent, respectively). Only stroke occurred more frequently in the CABG group (5.2 percent vs. 2.4 percent in the PCI group). "In patients with diabetes and multivessel coronary disease, CABG was of significant benefit as 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."

In order to give our patients the best possible outcomes, we continue to revise our guidelines for recommending CABG versus PCI, based on the latest and most persuasive available evidence. At present, the three groups of patients who are advised categorically that they should undergo CABG are:

- Patients with three-vessel CAD and diabetes mellitus;
- Patients with two-vessel CAD (with proximal or mid-LAD blockage) and diabetes and a SYNTAX score of 23 or higher; and
- Nondiabetic patients with three-vessel CAD and a SYNTAX score of 23 or higher.

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. The former is an invasive procedure by its very definition, and requires a hospital stay and involves a large incision, some pain and discomfort and a recovery period of weeks to months. The latter is usually done on an outpatient basis, with a small incision and a quick recovery and return to normal activities.

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 by what we call the Heart Team, consisting of an interventionalist, a surgeon and the patient's own cardiologist or primary care physician. In this setting, the patient can consider all the relevant factors and make the decision as calmly and unemotionally as possible. The patient's own doctor is a very important member of the team, because he or she knows the patient and what is going on in the patient's life.

Patients in the three groups described above might be excluded from CT surgery consultations if the following situations or comorbidities are present making them unsuitable, or inappropriate or high-risk for CABG:

PATIENT: Susan Sperling, 76-year-old woman

DIAGNOSIS: Unstable angina due to 90 percent blockage in left main coronary artery

TREATMENT: Intervention of left main ostium using orbital atherectomy and DES

"Besides being highly skilled, he's a doctor who really cares. That's not easy to find these days."

In 2013, I began having chest pain. It was on and off, not too severe at first. I didn't have a primary care doctor, because my old doctor had left his practice, so I ignored my symptoms for a while. Finally, though, I decided I had better find a new doctor and get my pain checked out.

In November I saw the doctor, who sent me to a cardiologist, who did some tests and said I was in serious trouble. He sent me to Dr. Sharma, who performed angiography and discovered that my left main artery was 95 percent blocked. I might very well have died if I hadn't finally paid attention to my symptoms!

Dr. Sharma performed orbital atherectomy to clear out my artery, and he discharged me in two days.

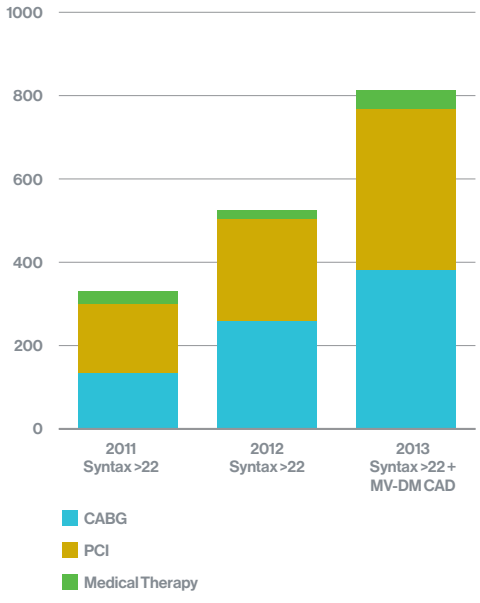
I am feeling fine now, and I am very grateful to Dr. Sharma. He is a wonderful doctor and a very kind man. After the procedure, I discovered that a few people I know had also been treated by Dr. Sharma, and they all feel the same way about him. Besides being highly skilled, he's a doctor who really cares. That's not easy to find these days.

- Acute MI (STEMI or non-STEMI)
- Age above 90 years
- Prior CVA or recent TIA (within one year)
- Severe COPD (FEV1 below 50 percent predicted) and on chronic bronchodilator therapy
- Body mass index (BMI) above 50
- LV ejection fraction below 20 percent
- Limited life expectancy of less than one to two year

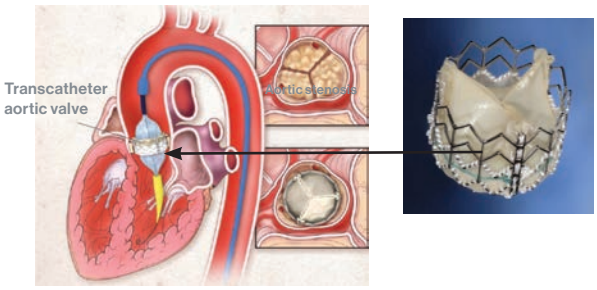
The graph at right shows that CABG is being performed for a higher percentage of these complex CAD patients at our medical center.

Mount Sinai is a participating center in a related study, the EXCEL (Evaluation of Xience Prime vs. CABG for Examination of LM Disease) Trial. This trial, which has enrolled 1,800 subjects at 165 centers worldwide, will evaluate whether PCI compared to CABG for treatment of left main stenosis (one-, two- or three-vessel disease and a SYNTAX score of 32 or less) plus other significant coronary lesions with the XIENCE Prime stent will result in noninferior or superior rates. The primary endpoint is a composite of death, large myocardial infarction or stroke at three years; the major secondary endpoint is a composite of death, MI, stroke or unplanned target vessel revascularization at three years.

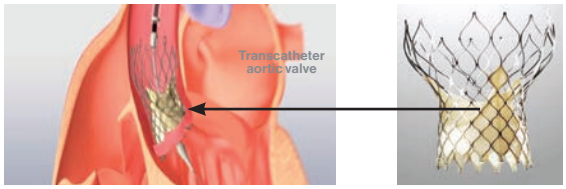
Revascularization Choices for High Syntax Score Patients at MSH



Percutaneous Heart Valves Available In U.S.



Edwards SAPIEN Valve



CoreValve

Approved Transcatheter Aortic Valves

	Edwards Sapien Valve	Medtronic CoreValve
First in man	June 2002	April 2004
Expansion	Balloon-expandable	Self-expandable
Frame	Stainless steel	Nitinol
Valve material	Bovine	Porcine
Sheath size	22-24 Fr	18 Fr
Aortic annulus	18-25mm	20-27 mm
Access site	Transfemoral, Transapical	Transfemoral, Subclavian, Direct Aortic

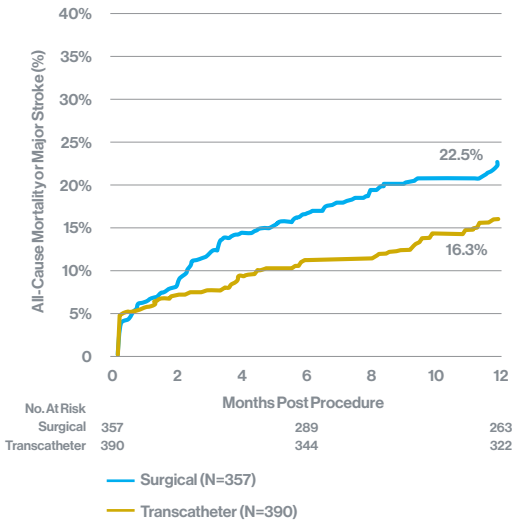
Update on Transcatheter Aortic Valve Replacement/Implantation

New data continue to support the safety and effectiveness of transcatheter aortic valve replacement/implantation (TAVR/TAVI).

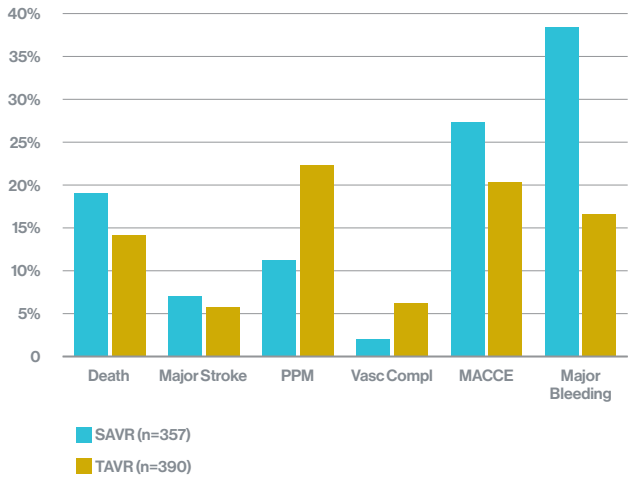
The PARTNER (Placement of Aortic Transcatheter Valves) Trial of the Edwards SAPIEN valve studied high-risk patients with aortic stenosis (Cohort A; n = 699) who were randomly assigned to transcatheter aortic valve replacement (TAVR) or surgical replacement (SAVR). One-year survival rates were similar. As we indicated in the 2013 Clinical Outcomes Report, two-year follow-up of these patients supported TAVR as an alternative to surgery. The two treatments were similar with respect to mortality, reduction in symptoms and improved valve hemodynamics, although stroke and paravalvular regurgitation was more frequent after TAVR and was associated with late mortality. Three-year follow-up data from PARTNER Trial A, reported in the spring of 2013, indicated that all-cause and cardiovascular mortality continued to be nearly identical between TAVR and SAVR. Stroke, a concern because of the higher rate observed at 30 days and one year, no longer favored the SAVR arm at three years.

The PARTNER Trial will continue to follow patients for five years to assess the durability and longer-term outcomes of TAVR. In a small trial of 111 patients, five-year follow-up showed valve degeneration of only 3.4 percent.

CoreValve Pivotal Trial: All-Cause Mortality or Major Stroke



CoreValve Pivotal Trial: 1-Year Results



PATIENT: Mohammad Aleem, 62-year-old man

DIAGNOSIS: Crescendo angina due to extensive CAD including left main and total coronary occlusion

TREATMENT: Intervention of left main, LAD-proximal and mid and LCx with three drug-eluting stents. Second-stage interventions of chronically occluded RCA with two drug-eluting stents.

"He cleared two arteries and I was out of the procedure room in an hour."

"In 2007, when I was living in Pakistan, my native country, I began to experience chest pain. I was told I had a blocked artery and I needed open heart surgery, but I declined, opting for medication instead. My pain increased, and when I came to the United States in 2009 I saw another doctor, who sent me to a New York City hospital for angiography.

"I had a very bad experience in that hospital. After the angiography I was seeing double and couldn't walk a straight line. They did many tests and found nothing wrong, except for my heart; again I was told I needed open heart surgery, but after three days my vision and my balance were normal again and I checked myself out.

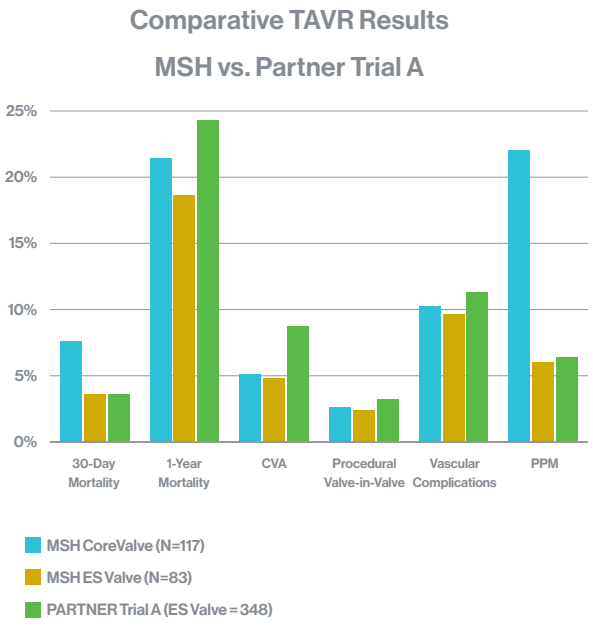
"I told a friend about my problem, and he recommended Dr. Sharma. He said Dr. Sharma had helped his father, who had a bad heart, without doing open heart surgery. I called him and told him my story, and he was very sympathetic and kind. He booked me into the Cath Lab right away.

"The first procedure Dr. Sharma performed was very quick. He cleared two arteries and I was out of the procedure room in an hour. He told me I would need a second procedure, which would be more difficult, because one of my arteries was 100 percent blocked, but he was confident that he would be successful.

"That procedure lasted four hours, but I recovered quickly and I have felt fine ever since. I work in a filling station pumping gas seven days a week, on my feet all day, so I need a healthy heart. I am very grateful to Dr. Sharma for fixing mine."

Mount Sinai is a principal site for the Medtronic CoreValve® U.S. Pivotal Trial. The trial, with a total of 1,500 subjects, has two arms: patients at high risk were randomized to receive either the CoreValve or surgery, and patients at extreme risk were not randomized and received the CoreValve. About two-thirds of the subjects were in the high-risk arm. Patients at high risk must be enrolled in the study to receive the CoreValve. Early in 2014, however, the Food and Drug Administration (FDA) granted approval of the CoreValve for patients at extreme risk after reviewing clinical outcomes, which demonstrated high rates of survival and some of the lowest rates of stroke and valve leakage reported.

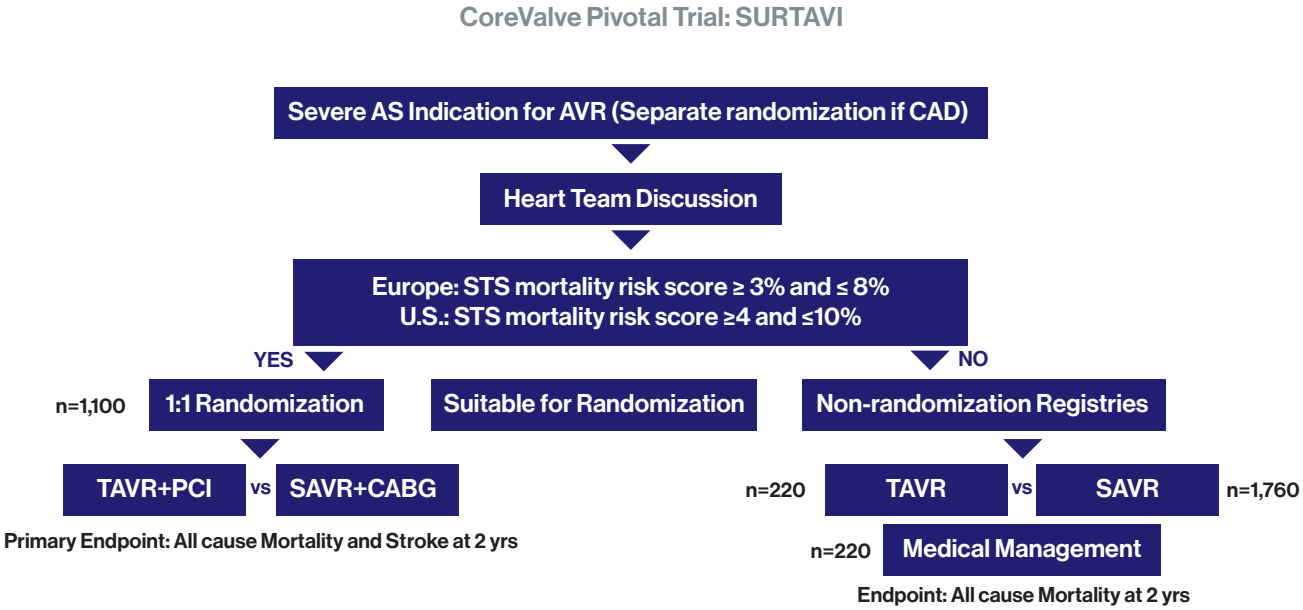
The first CoreValve transcatheter aortic valve implantation procedure in the United States was performed at Mount Sinai, on December 17, 2010, by Samin K. Sharma, MD, and David H. Adams, MD, Chair of Cardiothoracic Surgery. The patient was an 88-year-old man with recurrent heart failure brought on by severe aortic stenosis who was at extreme risk for surgery. His aorta was highly calcified, and CoreValve implantation was deemed the only option to prolong his life. This patient is still alive and well more than three years after the TAVR procedure.



The CoreValve trial in extreme-risk cases was presented at Transcatheter Cardiovascular Therapeutics (TCT) in 2013 and showed very favorable outcomes. At the Annual Scientific Session of the American College of Cardiology (ACC) on 2014, Dr. Adams presented the CoreValve trial in high-risk patients and showed that CoreValve patients had lower mortality and CVA compared to SAVR patients.

The CoreValve and the SAPIEN valve, which is now approved by the FDA for implantation in extreme-risk inoperable and high-risk patients, are comparable in many ways, although the SAPIEN requires a large 22-French or 24-French sheath, compared to 18F with the CoreValve. The CoreValve can be used in many patients whose anatomy cannot accept a 22F or 24F sheath as well as patients with a large annulus.

By November 2013, 200 transcatheter aortic valve replacement procedures had been performed at Mount Sinai, often with better results than were achieved in the PARTNER Trial. In a comparison of Mount Sinai's first 200 cases (CoreValve n = 117; Edwards SAPIEN valve n = 83) with patients in Cohort A of the PARTNER Trial who received the Edwards SAPIEN valve (n = 348), while 30-day mortality was 7.6 percent for the CoreValve,



PATIENT: Frances Laino, 83-year-old woman

DIAGNOSIS: Acute on chronic diastolic heart failure due to severe aortic stenosis

TREATMENT: Transcatheter aortic valve implantation using 29mm CoreValve in 2011

"With Dr. Sharma I knew right away that I was in good hands."

"For a long time I had a slight heart murmur, but it slowly got worse, and in 2010 my cardiologist told me that my aortic valve was failing. He said that my valve could be replaced with open heart surgery, but at my age he did not think I was a good candidate for that procedure. He recommended that I see Dr. Sharma at Mount Sinai. If I was eligible for a clinical trial they were running, he said that Dr. Sharma could replace my valve without opening my chest.

"With Dr. Sharma I knew right away that I was in good hands. He was so pleasant, and he carefully explained the procedure for replacing my valve, which sounded like a wonderful alternative. I was very relieved and happy that I would not have to undergo open heart surgery.

"I did qualify for the trial, and the procedure went as smoothly as he had promised. After two days I was home again. I had no pain or discomfort, and I could shower, make my bed, lead a normal life. Since my valve was replaced [three years ago] I have had my gall bladder removed, and I had a serious fall in a restaurant and broke my thigh bone, but my heart is fine. I see Dr. Sharma once a year, and he is always genuinely glad to see me, and glad to see that I'm doing well. Every chance I get, I recommend Mount Sinai and Dr. Sharma."

3.6 percent for the SAPIEN valve at Mount Sinai compared with 3.4 percent in the PARTNER trial, one-year mortality was 21.4 percent for the CoreValve, 18.6 percent for the SAPIEN valve at Mount Sinai compared to 24.3 percent in the PARTNER Trial, and 30-day stroke incidence was 5.1 percent for the CoreValve, 4.8 percent for the SAPIEN valve at Mount Sinai versus 8.7 percent in the PARTNER trial.

Mount Sinai is also a participating center for the Medtronic CoreValve Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) trial, the largest global, randomized, controlled trial to evaluate transcatheter aortic valve implantation in less sick, intermediate-surgical-risk patients who are typically treated with open-heart surgical aortic valve replacement. The trial will enroll about 2,500 subjects and evaluate whether the CoreValve is noninferior to surgical valve replacement based on the composite primary endpoint of all-cause mortality and disabling stroke at 24 months.

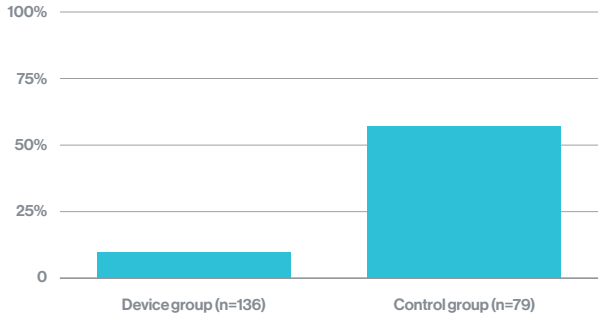
Paravalvular leak (PVL) is a frequent complication of transcatheter aortic valve replacement (TAVR) and is seen at a much higher rate after TAVR than after conventional surgical aortic valve replacement. A variety of devices are in development, featuring new designs and improved technologies that hold promise for minimizing PVL after TAVR.

EVEREST II (Endovascular Valve Edge-to-Edge Repair) Study

Primary Endpoints Per Protocol Cohort

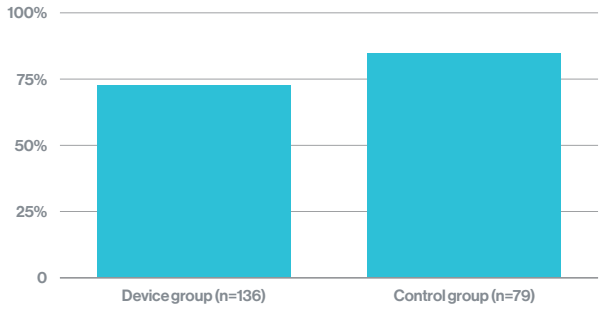
SAFETY

Major Adverse Events – 30 days



EFFECTIVENESS

Clinical Success Rate* – 12 months



*Freedom from the combined outcome of death, MV surgery or re-operation for MV dysfunction, MR >2+ at 12 Month

Percutaneous Reduction of Mitral Regurgitation

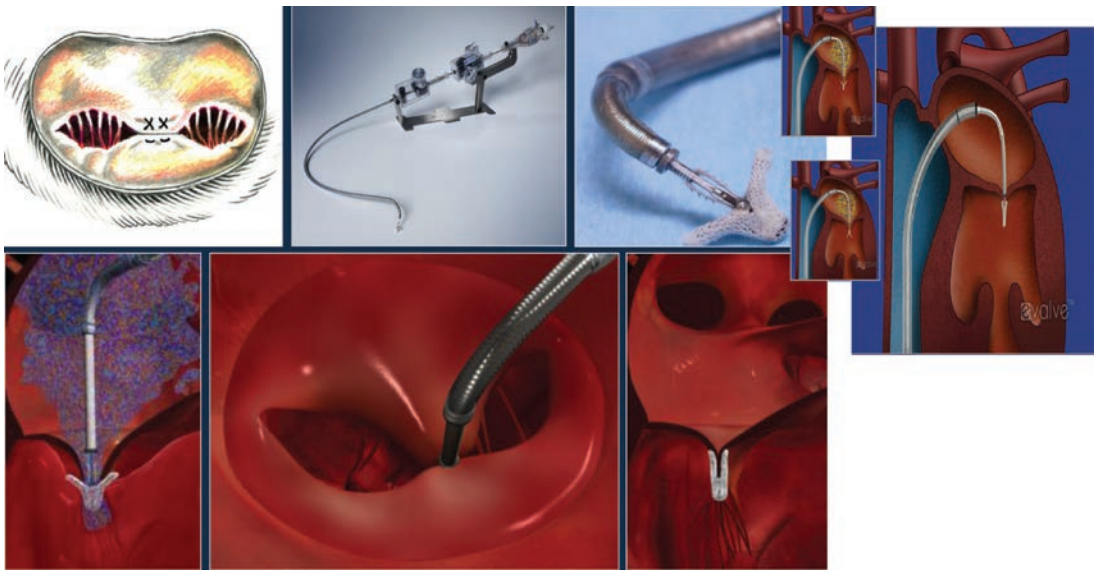
When mitral valve regurgitation (MR), a commonly encountered valve disorder, is present, blood flows backward through the mitral valve when the heart contracts. This reduces the amount of blood that is pumped out to the body.

Transcatheter therapies are being developed to treat this condition. In the EVEREST (Endovascular Valve Edge-to-Edge Repair Study) II Trial, treatment of mitral valve regurgitation with the MitraClip® was compared with surgical mitral valve repair in 191 patients who received the device in a 2:1 ratio. Four-year results showed that patients who received percutaneous treatment more commonly required surgery to treat residual mitral valve regurgitation; however, after the first year of follow-up, there were few surgeries required in either group, and no differences in the prevalence of moderately severe or severe MR or mortality at four years.

For patients with functional mitral valve regurgitation who were not candidates for surgical mitral valve repair, the prognosis has not been good; as a group they have experienced frequent rehospitalizations and high mortality without any effective treatment. A study that is under way, the COAPT (Clinical Outcomes Assessment of the MitraClip Percutaneous Therapy) Trial, will evaluate the role of the clip against the standard of care in patients with functional mitral regurgitation who are at extremely high risk for mitral valve surgery. The trial will enroll up to 420 patients at as many as 75 medical centers in the United States.

MitraClip has now been approved for clinical use in high-risk MR patients who are ineligible for surgical correction.

Catheter-Based Mitral Valve Repair MitraClip System



COAPT: Trial design

~420 Patients to be enrolled at 75 U.S. sites

Significant FMR (≥3+ by core lab) high risk for mitral valve surgery specific anatomical criteria

RANDOMIZE 1:1

MitraClip n=210

Control Group Standard of Care n=210

Clinical and TTE Follow-up: 1, 6, 12, 18, 24, 36, 48, 60 months

Innovations

Annapoorna S. Kini, MD, MRCP, FACC

To view a complex case of PCI of LAD/diagonal bifurcation with a dedicated two-stent approach, scan the QR code below or visit http://www.cccsymposium.org/2013-livecase05.html

ABSORB Bioresorbable Vascular Scaffold (BVS)

The Abbott Absorb® Bioresorbable Vascular Scaffold is a new technology developed in response to concerns regarding in-stent restenosis even after a few years in first-generation drug-eluting metal stents. The Absorb BVS is made of polylactide, a material also used for dissolving sutures. It is inserted by an interventional cardiologist in a catheterization procedure and delivers the medication as the DES does, once the drug dissolves the DES (metal portion) remains in the vessel permanently, although the support is only needed for several months. The BVS, on the other hand, begins to dissolve in two years and is completely dissolved into the artery wall in three years, leaving behind only two pairs of tiny metallic markers to indicate where it was implanted.

With a metal stent in place, a coronary vessel does not dilate and constrict depending on the body's needs in the normal physiological way. The randomized ABSORB III clinical trial, now under way, which has a primary endpoint of target lesion failure at one year, will also evaluate in a subset of patients novel endpoints such as vasomotion, a measure of how much natural motion returns to the vessel as Absorb dissolves into the arterial tissue.

PATIENT: Elise Gelpi, 68-year-old woman

DIAGNOSIS: Crescendo angina/intermediate coronary syndrome

TREATMENT: Intervention of left main ostium with implantation of DES

"My recovery is going smoothly, and I am eager to get back to my work."

"In the fall of 2013, I was suffering from some mild pain and discomfort in my chest, and I also seemed to be tired all the time. I visited a cardiologist recommended by my internist, and she said she wanted to send me to Mount Sinai by ambulance for an angiogram. I don't remember whether the flashing lights and siren were on, but I do know we were traveling very fast, which was a bit alarming. Could my condition be that serious?

"At the Cath Lab, people sicker than I were in line for procedures, and as I waited with my husband my apprehensiveness increased. This was a new and scary experience for me. At last it was my turn, and a lovely woman appeared beside me and said, 'I'm Dr. Kini, and I'm going to take good care of you.' That was very reassuring.

"She performed the angiogram, and she told me that my left main artery was 80 to 90 percent blocked. That was something I never expected, although perhaps I should have; my father and his father and *his* father died very young of heart disease. I was wheeled out of the procedure room and given my options: placement of a stent or open heart surgery. Dr. Kini and a surgeon explained the risks and benefits, and my husband and I weighed them with the guidance of my internist (on the telephone). We decided on a stent, which Dr. Kini would implant, and I am confident that it was the right decision.

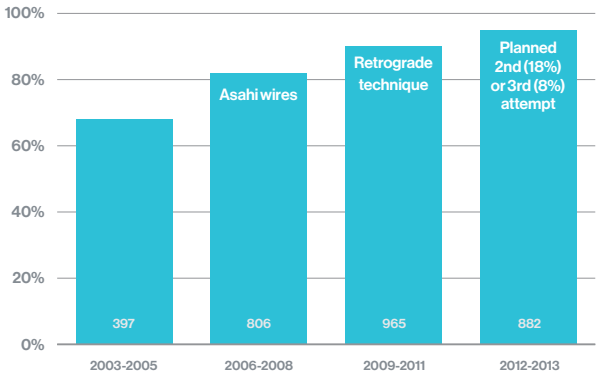
"My recovery is going smoothly, and I am eager to get back to my work, in the field of antiques and art, particularly American art. I am very grateful to Dr. Kini and Mount Sinai. They are incredibly busy there in the Cath Lab, but everyone I came in contact with was unfailingly polite and kind.

"I see Dr. Kini for follow-up appointments, and I also see a Mount Sinai nutritionist, who is helping me follow a more heart-healthy diet. A stent in time saved my heart, and now I intend to take very good care of it."

There are two pairs of platinum marker beads - one pair at each end of the scaffold remain even after the BVS has been absorbed. The markers on the scaffold are aligned with the markers on the delivery catheter.

ABSORB III Trial: Preclinical Program ABSORB BVS Safety in PCA to 36 Months

Procedural Success of CTO PCI at MSH Mount Sinai Experience for last 10 years



EXPERT CTO Trial: 1-Year Outcomes (N = 221)

Overall procedural success	89.6%
Guidewire crossing successful	90.1%
Successful delivery of MINI-TREK balloon across CTO lesion	96.9%
Major adverse cardiac event	8.2%
Death	1.9%
MI	3.4%
Restenosis (TLR)	5.8%
Stent Thrombosis	1.0%

The clinical trial plans to enroll about 2,250 coronary disease patients across the country. It will compare the performance of Abbott's drug-eluting Bioresorbable Vascular Scaffold to the company's XIENCE™ family of drug-eluting stents. Both the stents and the scaffolds deliver the antiproliferative drug everolimus. One of the study centers, Mount Sinai enrolled 41 patients.

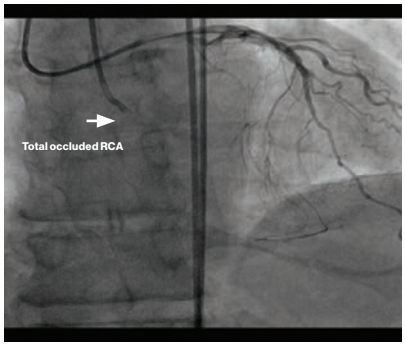
Internationally, clinical trials for Absorb began in 2006, with more than 1,000 patients receiving the device. It is now available for sale in Europe, the Middle East, parts of Latin America, India, Malaysia, Hong Kong and New Zealand, and preliminary data are encouraging.

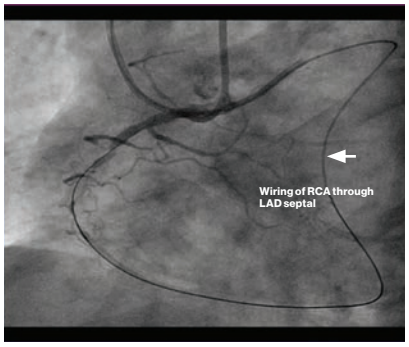
While research is ongoing on many fronts, heart disease remains the number one killer of Americans today. At Mount Sinai we believe that it is critically important to be part in every clinical trial to provide therapeutic option for our patients, including those treatments that are available on other continents. We welcome the opportunity to participate in clinical trials and potentially to advance the treatment of heart patients everywhere.

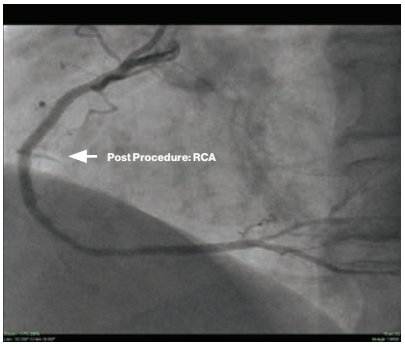
Update on Chronic Total Occlusion

A chronic total occlusion (CTO), a blockage present for more than 3 months, is a complex blockage of the coronary artery seen in 15-20 percent of patients who have coronary disease. Important factors that influence successful opening of this complex blockage include the length of the lesion and the presence of calcium, among others.

Newer wires have improved the success rate of crossing CTOs. Even after crossing the lesion in these complex lesions due to presence of calcium and tortuosity, delivery of initial angioplasty balloon is challenging. Balloon diameter and length is another factor to be considered. The diameter and length 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 and useful in crossing the CTO.







PATIENT: Santi Dhar, MD, 78-year-old man

DIAGNOSIS: Unspecified chest pain; coronary atherosclerosis of native vessel

TREATMENT: Complex intervention of LAD-proximal, LCx-OM1 and ramus intermediate

"I am a fit and active 78-year-old man, thanks to Dr. Kini and Mount Sinai."

"In August of 2013, I visited my gastroenterologist thinking I was suffering from severe reflux, but he believed instead it was acute coronary syndrome. He actually summoned an ambulance and sent me directly to Mount Sinai.

"I was a bit shook up because everything was happening so fast, but when I arrived at the ER I met Dr. Kini, who was very reassuring. Within half an hour they had performed an echocardiogram and I was being readied for angioplasty.

"Dr. Kini implanted one stent, and she explained to me that I would need three more stents, but she gave me clearance to travel to India for my son's wedding before the second procedure. I never would have gone without her permission, but she said I would be fine, and I was. A little breathless from time to time, but I enjoyed my trip.

"In October I had the second procedure, which went very smoothly, and my recovery was quick. Now I feel much better. I can exercise, swim, even walk around Manhattan with my daughter. I am a fit and active 78-year-old man, thanks to Dr. Kini and Mount Sinai."

We also need sufficient back up guide support. The "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. A combination of the Guideliner system and small balloons has improved our success rate with CTOs to 90 percent.

The EXPERT CTO trial (data at left) presented this year at ACC for the first time showed that in complex lesion subset of chronic total occlusion in expert hands the success rate was 90 percent. This trial tested small angioplasty balloons and two wires (Pilot family and Progress family).

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 95 percent.

Innovations

Pedro R. Moreno, MD, FACC

Pedro R. Moreno, MD, FACC

Director, Translational Research,
Cardiac Catheterization Laboratory

High-Risk Plaques and the Prediction of Major Adverse Cardiovascular Events

The concept that plaque rupture and thrombosis trigger acute myocardial infarction (AMI) has been well established, but there is still controversy over how to identify and treat rupture-prone lesions that may evolve into AMI.

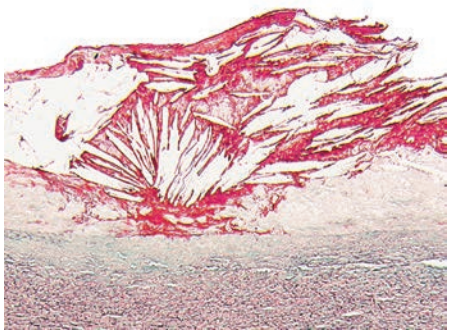
The landmark Ambrose and Fuster publication established that progression of coronary artery disease (CAD) to AMI occurs predominantly in non obstructive lesions. While this is true in the early stages, recent studies show plaque expansion precedes the acute event, as proposed by Narula et al. A lipid-rich lesion with increased plaque burden is susceptible to plaque rupture, independent of the degree of stenosis. If flow limiting, it may show symptoms and grow to an acute event. Fibrotic lesions, however, may not necessarily precipitate plaque rupture or thrombosis, independent of the degree of stenosis.

Current clinical guidelines and appropriateness criteria suggest that fractional flow reserve (FFR) may be critical in the decision-making process, but FFR provides limited information about plaque composition and may not identify lesions susceptible to plaque rupture and thrombosis. Thus, plaque characterization could prove superior to physiological testing, even when the lesion is symptomatic and obstructive.

Obstructive Disease and Chronic Stable Angina

Several randomized trials in patients with multivessel CAD established a five-year event rate of 16.9 percent for stents and 16.7 percent for surgical revascularization. The COURAGE Trial showed similar event rates at five years for percutaneous coronary intervention (PCI) and optimal medical therapy (OMT), 20 percent and 19.5 percent, respectively. Despite the increased rate of events compared to the randomized trials mentioned above, these reports were incorporated into clinical practice, because not every obstructive lesion required revascularization. The need for better risk stratification became clear.

A prospective test of FFR showed that 37 percent of obstructive lesions on angiography were FFR-negative. Avoiding PCI in these lesions resulted in a 5 percent reduction in major events at one year. Using FFR can easily identify the substrate of patients who will benefit from PCI. Nevertheless, when FFR-positive lesions were randomized to PCI versus OMT, there was no difference in terms of death or MI. An absolute 9.5 percent reduction in urgent revascularizations, however, prompted the Data Safety Monitoring Board (DSMB) to stop the trial prematurely. The number needed to treat (NNT) to prevent one urgent revascularization in FFR-positive lesions is 10.5. In other words, in order to prevent one episode of urgent revascularization, PCI must be performed in 10.5 FFR-positive lesions.



Example of atherothrombosis showing plaque rupture of a large necrotic-core lesion. (Courtesy of Dr. Purushothaman, The Mount Sinai Hospital 2014)

PATIENT: Enrique Cardenas, 63-year-old man

DIAGNOSIS: Crescendo angina/intermediate coronary syndrome, coronary atherosclerosis of native vessel.

TREATMENT: Successful intervention of LCx branch OM2 and placement of DES; successful intervention of LCx branch LP1 and placement of DES.

"Today my energy is back – I feel as if I'm in my thirties."

"I am an American citizen, but I had retired to Ecuador, my native country, when in December 2013 I experienced sharp, constant pain in my chest. At a hospital there I had an angiogram and was told that I had blockages in some of the arteries of my heart. An attempt was made to clear the blockages with angioplasty, but the doctors in Ecuador were unsuccessful. They told me that I needed open heart surgery, and I decided to return to New York, where the finest doctors are.

"I was referred to Mount Sinai, and there Dr. Moreno did an angiogram and advised me that my condition was so serious that I should undergo open heart surgery – right away. The next day, Dr. [Rama] Reddy performed quintuple bypass.

"My recovery was quick, and for a while I was feeling pretty good. But then I began to feel tired and I had a nagging pain to the right of my heart. It was always there – like having a pebble in my shoe. I was prescribed an angina medication, but it didn't help. So back I went to Mount Sinai and met Dr. Moreno.

"Dr. Moreno performed another angiogram and told me two more arteries were blocked. I really didn't want more open heart surgery, and Dr. Moreno said he believed he could clear the blockages and implant stents with angiography. I am a man of faith, and so is Dr. Moreno. We prayed together while I was on the table, before he began, and afterward he told me the procedure went surprisingly smoothly. Given the severity of my condition, I know God was guiding his hands.

"Today my energy is back – I feel as if I'm in my thirties. I am exercising, eating right, taking my medication, trying not to get angry or stressed. From the bottom of my heart, I thank Dr. Rama Reddy, Dr. Moreno and the entire Mount Sinai Cath Lab staff."

Despite these findings, FFR-positive lesions may still be suitable for regression with aggressive lipid-lowering therapy. This was the rationale for the YELLOW Trial, which randomized FFR-positive nonculprit lesions to 40 milligrams of rosuvastatin versus traditional statin therapy. The primary objective was a reduction in lipid content. After seven weeks of therapy, lesions randomized to the intensive therapy group showed a significant reduction in lipid content. Importantly, no change was observed if the plaque was fibrous to begin with.

The clinical benefits of FFR-guided PCI are evident, but death and MI are still not tailed apart by functional testing. Further, not all FFR-positive lesions will benefit from revascularization. FFR by itself cannot go further. Risk stratification should improve over quantitative measurement of luminal stenosis by using qualitative assessment of plaque composition.

Intracoronary imaging will help identify lesions at risk for rupture and thrombosis by documenting large necrotic-core thin-cap fibroatheromas with plaque burden greater than 70 percent. This is the rationale for the PROSPECT II trial. In addition, fibrotic lesions may be properly treated by OMT. These lesions may not cause a great penalty for future death and myocardial infarction. If clinically refractory to OMT, however, PCI will offer an alternative to avoid progressive symptoms.

Innovations

Prakash Krishnan, MD, FACC

Prakash Krishnan, MD, FACC
Director, Endovascular Intervention

To view a complex endovascular case, scan the QR code below or visit http://www.cccsymposium.org/2013-vascular-livecase01.html

Drug-Eluting Balloons (DEB) for Treatment of Peripheral Artery Disease

We at The Mount Sinai Hospital regularly adopt innovations based on clinical outcomes and experience. Peripheral artery disease (PAD) is a difficult and resistant disorder that contributes to significant morbidity in patients. Each year new technology is taking its place in the treatment of PAD, but restenosis of the peripheral arterial lesions has been an Achilles heel. The advent of drug-coated balloons and drug-coated stents has changed the dynamics and approach to PAD. We have adopted innovations based on the outcomes shown and experience.

A 65-year-old female patient with a past medical history of hypertension, diabetes mellitus type II, hyperlipidemia, peripheral arterial disease, breast cancer, S/P lumpectomy, CAD s/p CABG came in with complaints of claudication in the bilateral lower extremity (Rutherford Grade I category 3). The patient underwent ABI with the result of 0.69 bilaterally and PVR suggestive of severe SFA disease. Doppler showed evidence of 90 to 99 percent distal SFA stenosis. The patient underwent a lower-extremity angiogram, which showed bilateral distal SFA 95 percent stenosis with two-vessel runoff distally. Successful PTA of the right distal SFA was performed with significant relief of symptoms in the right lower extremity on follow-up.

1. THUNDER trial: Prospective, randomized, multicenter study compared the use of a paclitaxel/iopromide-coated balloon (n = 48) with POBA (n = 54). Showed significant reduction of the angiographic late lumen loss at six months for the actively coated balloon (0.4 ± 1.2 vs. 1.7 ± 1.8 mm, P< .001). TLR rates reduction sustained until two years.
2. FEMPAC trial: Total patient number of 87 randomized 1:1 into the two treatment arms: drug-coated balloon versus standard balloon angioplasty. Study showed a reduction in late lumen loss (0.3 vs. 0.8 mm, P = 0.031).
3. LEVANT I study: Study of MOXY ™ vs. PTA showed similar reduction on LLL as compared to prior studies (P = 0.016).
4. LEVANT II study: At six months primary patency of the treated vessel was higher among patients treated with a DEB (92.3 percent vs. 82.7 percent). Patients treated with a DEB experienced similar freedom from major adverse events compared to the PTA group (94.0 percent in the DEB group and 94.1 percent in the PTA group). Repeat revascularization rates at this interim time point were low and consistent among both groups.

PATIENT: Melba Conley, 65-year-old woman

DIAGNOSIS: Superficial femoral artery stenosis

TREATMENT: Percutaneous transluminal angioplasty with DES of SFA

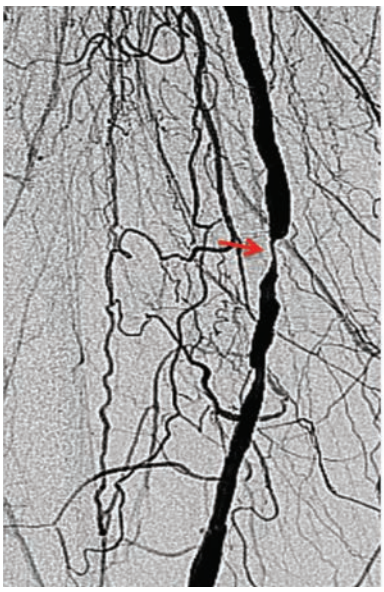
"I had the procedure, and I'm doing well. I can walk eight or nine blocks without stopping to rest."

"I'm 65 and still alive, but I have had my share of health problems. I've been treated for cancer, and in 2011, I had coronary artery bypass surgery. About that time, I developed pain in both legs that got progressively worse. That's when I first saw Dr. Krishnan. He explained that atherosclerosis affects all the arteries in my body and that I was at increased risk for complications of atherosclerosis.

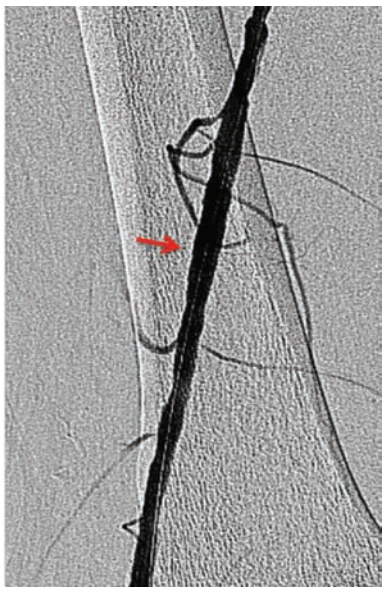
"He performed a simple test called an ABI (ankle brachial index) to diagnose my condition. He said my arteries in both legs were blocked and he would have to clear them. He performed procedures on my legs with the Rotablator, first one leg and then the other, and I was walking farther and feeling better. But after about one year my legs started bothering me again, and ultrasound showed that the blockages had returned. Dr. Krishnan explained that that I was a good candidate for a newer technology as part of a study of the use of a balloon coated with medicine to prevent the recurrence of the blockage.

"I had the procedure, and I'm doing well. I can walk eight or nine blocks without stopping to rest, and recently I even traveled alone by train from New York to Pennsylvania. Dr. Krishnan told me I need follow-up ultrasound for my legs, as this treatment was a part of a trial and the results are being strictly monitored. He is an amazing doctor and I have complete faith in him. I tell my children, 'If Dr. Krishnan says to do it, it's a done deal.'"

Before Angioplasty



After Angioplasty



Innovations

George Dangas, MD, PhD, FACC, FSCAI

George Dangas, MD, PhD, FACC, FSCAI
Director, Cardiovascular Innovation

Self-Expanding Stents

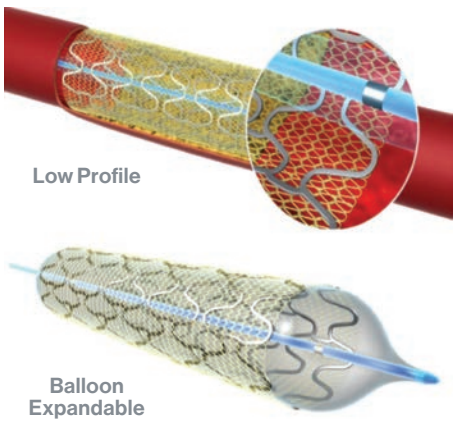
The drug-eluting coronary stent has served interventional cardiologists and their patients very well for about a decade in terms of preventing restenosis, and it continues to evolve and improve, with more biocompatible polymers and more advanced drug delivery systems. Excellent long-term results are associated with important considerations upon implantation, including appropriate stent length; appropriate diameter; appropriate balloon expansion; and verification with angiographic as well as more highly sophisticated intravascular imaging techniques to ensure that the stent has a natural inflow and outflow without any microdissections of the coronary arteries at the edges.

While a stent has a uniform diameter, coronary arteries taper. When treating a lesion of an unknown diameter or a long length with a stent, there can be a discrepancy between the diameters of the proximal and the distal areas of interest. If the stent is sized to the distal end, it can be underexpanded at the proximal end, and if sized to the proximal end, it can cause a microtear at the distal end. One solution is to use balloons of different sizes to expand the distal and proximal ends. Another solution might be the bioabsorbable stent, although for a period of several months before they are absorbed the problems are operational.

The self-expanding stent first was applied in percutaneous coronary intervention in 1986, but because of thrombosis and other complications it fell into disuse in that arena. It was not clear, however, whether these complications were due to the self-expansion property, the thickness of the struts, implantation techniques or anti-clotting medications. Self-expanding stents have been approved for use in vascular arenas: the carotids and arteries and veins of the extremities, particularly when we treat very long segments.

The next generation of self-expanding stents bears little resemblance to the 1986 model. Significant progress has been made in perfecting it, in terms of miniaturization and delivery profile, and several types of vascular self-expanding stents by different manufacturers have now been approved for investigational use. A more dynamic device than classic stents, the nitinol-type stent is deployed via sheath retraction rather than balloon expansion. It expands slowly, smoothly and gradually, assuming the diameter of the vessel on its own, minimizing a mismatch and the risk of a tear or underexpansion. If a clot is absorbed after the procedure ends, the stent will not be left bare but will continue to expand and attach to the vessel wall.

M-Guard Self-Expanding Stent



PATIENT: James Grossman, 72-year-old man

DIAGNOSIS: Crescendo angina due to stenosis in left anterior descending artery

TREATMENT: Implantation of bare metal stent to LAD

"He is attentive to his patients, approachable and friendly, and he is a brilliant physician. To my mind, in his field there is nobody better."

"I met Dr. Dangas in the 1990s through my work in public relations. I would often call on Dr. Dangas when an authoritative voice was needed in the field of cardiology. We had a very collegial working relationship.

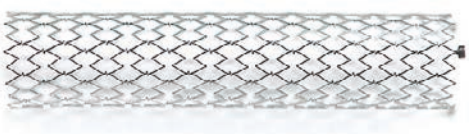
"In 2002, we embarked on a doctor-patient relationship when I began having chest pains and was sent for angiography. At that time drug-eluting stents were still being studied and could only be implanted in patients enrolled in a clinical trial, so I received a bare metal stent in my left anterior descending artery, which was 70 percent blocked.

"Only two years later, a routine stress test and an echocardiogram revealed restenosis within the stent itself. The drug-eluting stent had by then received FDA approval, and Dr. Dangas implanted it inside my bare metal stent.

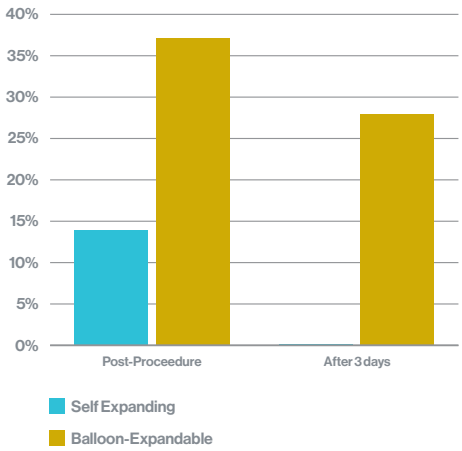
"Since that time, I have been fortunate not to require any further procedures at all. I still see Dr. Dangas for regular checkups, and he monitors my high blood pressure. Dr. Dangas is Greek, and although I am Jewish, I grew up in a Greek neighborhood in a little town near Pittsburgh. I always say I am Greek by association. But that is not the only reason Dr. Dangas and I are simpatico. He is attentive to his patients, approachable and friendly, and he is a brilliant physician. To my mind, in his field there is nobody better."

As mentioned earlier, DES technology has served us well and will continue to do so. It has no major flaws and, continuous research and innovation have improved them a great deal. Patients have long-standing, durable results and symptom relief. We continue, however, in our quest to restore coronary arteries to their smooth, natural contours. Self-expanding as well as self-absorbing stents may turn out to be very important steps.

STENTYS Self-Expanding Stent



% Malapposed Stents



Innovations

Joseph M. Sweeny, MD

Joseph M. Sweeny, MD

Associate Director, Interventional Cardiology Fellowship Program

Coronary Revascularization in Diabetics

Patients with diabetes are at much higher risk for developing coronary artery disease (CAD) and have a higher risk of suffering a myocardial infarction than non-diabetics. Diabetics represent 25 to 30 percent of all patients undergoing coronary revascularization. They often present with advanced coronary atherosclerosis, because, among other reasons, many diabetic patients have asymptomatic cardiovascular disease due to neuropathy that prevents them from experiencing the typical symptoms of chest pain and seeking medical attention.

For years, we have worked to determine the best revascularization strategy for diabetic patients with extensive CAD: percutaneous coronary intervention (PCI) or coronary artery bypass surgery (CABG). The former is a minimally invasive procedure, on an outpatient basis, with a quick recovery. The latter is a more risky, sometimes open-chest surgical procedure with a hospital stay and a longer recovery period. But the outcomes are the most important factor in choosing a strategy.

Some small trials showed a real advantage for diabetics with CABG, in terms of a lower incidence of major events, but those studies were conducted when PCI was still in its infancy. One of these, the BARI (Bypass Angioplasty Revascularization Investigation) Trial, which showed a survival advantage of bypass over PCI, was conducted back in the era of the bare metal stent. The field of PCI has advanced considerably, with better stents, balloons and adjunctive therapies. Clearly a new study was needed. [The five-year results of that new study were published late in 2012, and they are compelling enough to influence clinical practice.]

The NHLBI-sponsored Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease (FREEDOM) Trial began enrolling patients in 2007. Mount Sinai was the international clinical coordinating center for this large outcomes trial, which compared PCI intervention using drug-eluting stents to CABG in diabetic patients with multivessel disease. A total of 1,900 diabetics with at least 70 percent stenosis in two or more major coronary vessels were enrolled at 140 centers worldwide. (Three-vessel disease was found in 83 percent.) Patients were followed for at least two years.

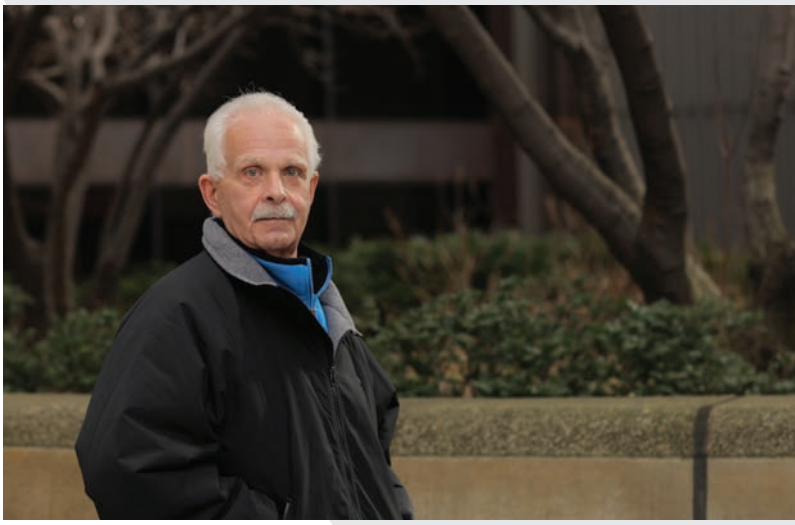
Published online and in the *New England Journal of Medicine*, the study found that for the primary composite endpoint of death from any cause, nonfatal MI, or nonfatal stroke, five-year rates were 18.7 percent with CABG versus 26.6 percent with stenting (although there were more strokes in the CABG group soon after the procedure). That included a rate of myocardial infarction of just 6.0 percent compared to 13.9 percent among the group that received stents. The risk of repeat revascularization was 12.6 for PCI versus 4.8 for CABG.

As it had done after the BARI Trial two decades earlier, the NHLBI issued an alert after the FREEDOM Trial results were made public recommending CABG as the preferred revascularization method for multivessel disease in diabetics.

PATIENT: Thomas Cacavio, 61-year-old man

DIAGNOSIS: Three-vessel coronary artery disease; moderate systolic left ventricular dysfunction

TREATMENT: Patient referred for coronary artery bypass graft surgery



"Now I'm feeling fine. I'm so glad to have found a cardiologist I like and trust, and one who knows all about my case."

"I have COPD, but otherwise I considered myself to be in fairly decent shape. Last August, however, I was working outside when I became light-headed and actually passed out. I came to quickly, and when I went inside to tell my wife I passed out again. In a panic, she called 9-1-1, and an ambulance came and brought me to a hospital near my home in Westchester."

"Based on the initial tests done, doctors there said the problem was with my heart and decided to transfer me to Mount Sinai. There were other patients who needed ambulances more urgently than I did, though, and it was nearly midnight when I arrived. Dr. Sweeny was there waiting for me, and we clicked right away.

"After performing angiography he told me that I had a number of problems with my heart: two of my arteries were 100 percent blocked and another was 90 percent blocked. I would need triple bypass surgery. Plus, two of my heart valves appeared to need repair.

"Bypass surgery was performed at Mount Sinai a week later. Having gotten a close look at them, the cardiothoracic surgeon said we could take a 'wait and see' attitude with my valves, which was a relief. During my recovery, Dr. Sweeny saw me every day, and he took care of me when I came back twice in November, first for what I was afraid was my heart but turned out to be gastritis, and next because I was running a high fever.

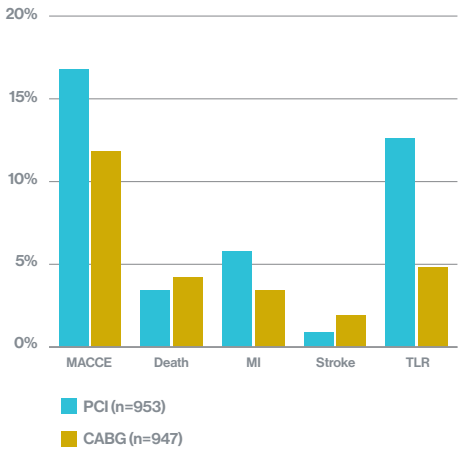
"Now I'm feeling fine. I'm so glad to have found a cardiologist I like and trust, and one who knows all about my case, because it appears I will need continuing care. My wife feels the same way about him – in fact, now Dr. Sweeny is her cardiologist, too."

Several mechanisms have been proposed to explain why diabetics are at greater risk for CAD. One theory is that because diabetes is a systemic disease, the atherosclerotic process is more diffuse (rather than focal), and consequently many patients with diabetes have left main coronary artery lesions and diffuse multivessel CAD. Research in this area is ongoing.

Following new guidelines put in place after the release of the study data, the diabetic patient who is found to have multivessel disease during a diagnostic cardiac catheterization is taken off the catheterization table and moved to a recovery area. When any sedation has worn off, the family is called in, and the heart team, composed of the interventionalist, a cardiothoracic surgeon and the patient's own cardiologist, calmly and objectively presents the risks and benefits of PCI versus CABG in that particular patient. Patients tend to be resistant to the idea of CABG at first. The data, however, is very persuasive: diabetics with multivessel disease undergoing CABG have better cardiovascular outcomes compared to those undergoing PCI.

The patient's doctor is a very important member of the team, because he or she knows the patient. And then there is the patient, who is perhaps the most important member of the heart team. Within the bounds of safety, after all the evidence has been presented, the patient's decision must be honored.

FREEDOM Trial: MACCE at 12 Months



Innovations

Sean P. Pinney, MD, FACC

Sean P. Pinney, MD, FACC

Director, Advanced Heart Failure
and Cardiac Transplant Program

Left Ventricular Assist Devices

In 1964, the National Heart, Lung and Blood Institute (NHLBI) launched the Artificial Heart Program. The aim was to develop pumps that could support the circulation particularly for those patients who could not be weaned from the heart-lung machine after heart surgery. Following some early successes, the NIH called for proposals for pumps that could be implanted and support patients for years of life as a therapy for heart failure.

In 2000, the REMATCH trial was conducted by the NHLBI to compare long-term implantation of left ventricular assist devices (LVADs) with optimal medical management for patients with end-stage heart failure who did not qualify for transplantation because of age or comorbidities. Based on the results of this study, Medicare coverage has been expanded to include this as destination therapy.

LVADs are approved for two indications — as a bridge to heart transplantation for patients on the waiting list, or as an alternative to heart transplantation, a destination therapy for patients whose advanced age or comorbidities make them unsuitable for transplant. When choosing patients for LVAD therapy, we look at who is going to derive the most benefit from these devices.

It is clear that people in the worst shape going into LVAD surgery tend to come out of the operating room with a higher risk for death than elective patients. Here in the Cath Lab, we may place a temporary VAD in patients in cardiogenic shock, to restore an adequate amount of blood flow to vital organs until patients can withstand further surgery, either the implantation of a durable LVAD or a heart transplant.

These temporary support devices fall into two basic categories: the intra-aortic balloon pump (IABP) and the percutaneous ventricular assist device. The balloon pump inflates in the aorta, helping to push blood into the coronary arteries, and then deflates, dropping the pressure against which the heart has to pump. The temporary LVAD (e.g., the Impella 2.5) pulls blood from the left ventricle and expels it from the catheter into the ascending aorta. Another temporary LVAD is the TandemHeart®. This device pulls oxygenated blood from the left side of the heart and returns it to the body.

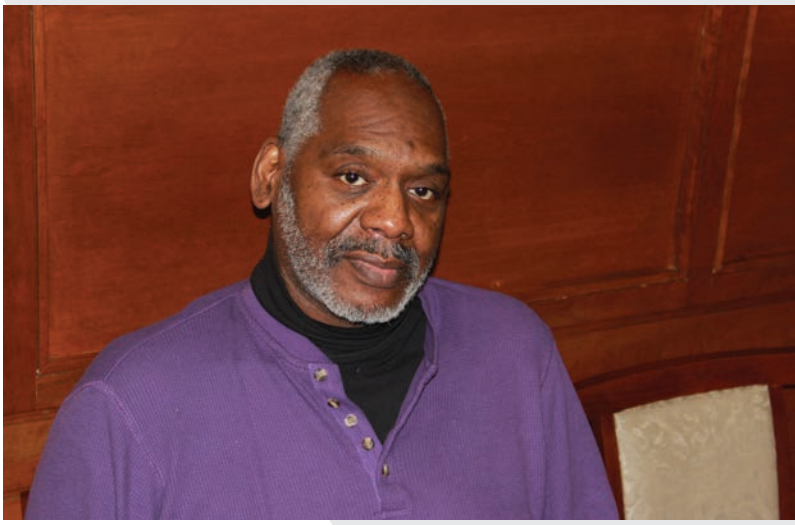
Although percutaneous pumps appear to have the edge over the IABP in terms of improving hemodynamics, comparative studies have been inconclusive. This may be because of the small numbers of subjects in the studies, or because cardiogenic shock is a very complex condition where restoration of adequate blood flow is a necessary but not necessarily sufficient requirement for recovery.

In some parts of the U.S., the wait for a heart transplant can be as short as a week. On the heavily populated west and east coasts, particularly in New York, the wait can be considerably longer. New York State is ranked 49 out of 50 in terms of registered donors. And because of the limited time that the heart can remain out of the body, hearts are allocated to nearby transplant centers first.

PATIENT: Michael Artis, 62-year-old man

DIAGNOSIS: Dilated cardiomyopathy

TREATMENT: HeartMate II® Left Ventricular Assist Device



"They were like loving parents – their concern was absolutely genuine."

"In August of 2011, after I passed out and my ICD [implantable cardiac defibrillator] shocked my heart, I went to a local hospital. I had the ICD because my heart was failing, and in fact I had been on the waiting list for a donor heart since the previous year. I felt I was getting very bad care at that hospital, so I signed myself out and made an appointment with Dr. Pinney.

"I thought I was just going in for a consult, but he admitted me to Mount Sinai and two days later I received an LVAD [left ventricular assist device]. I had some bleeding issues with the LVAD, so I was in and out of the hospital, but still I felt much better and was able to be more active. I would definitely say the LVAD saved my life.

"Finally in May of 2013 I got the call telling me they had a heart for me. My reaction was that I wasn't ready, although I can't say I was scared. I felt very safe with the LVAD keeping my old heart beating. But my sister wouldn't hear of it when I suggested that maybe I should pass on the donor heart. So back I went to Mount Sinai.

"I can't say enough about the heart team, including Dr. Pinney, the surgeon, Dr. Anelechi Anyanwu, and Kim Ashley, the coordinator. Their support got me through it. They were like loving parents – their concern was absolutely genuine.

"The operation went smoothly, and so did my recovery. At first, without the LVAD, I felt vulnerable, but now I have confidence in my new heart. I'm still doing rehab, and I go back to Mount Sinai every month for clinic and every two months for a biopsy. I thought after the transplant I would be under the care of my regular cardiologist, but the heart team said, 'Oh, no, you're our patient for life.' That's just fine with me."

This shortage means that more patients are relying upon implantable LVADs. The pump is implanted in the upper part of the abdomen and functions as a mechanical heart, pulling blood from the left ventricle and sending it to the aorta for delivery to the rest of the body. A tube attaches the pump to a battery and control system worn outside the body.

The survival rate at one year with the implantable LVAD is 80 percent, decreasing about 10 percent each year. As more centers across the country are implanting these devices, and our experience has grown, the patient on an implantable LVAD now has about a survival window of about 3 to 5 years, and some patients have been on it for eight years. At Mount Sinai Heart, our longest surviving patient has been on the HeartMate II for more than three years, and is doing very well. She is waiting for a donor heart, but as for many on the transplant list, that dream may not be realized.

What does the future hold? For the temporary support devices, it's a case of evolution: making them smaller, easier to insert, more durable, safer. For the implantable LVAD, will the trend be toward a compact and completely rechargeable artificial heart, or a multiplicity of devices tailored for patients' individual needs? Time will tell.

Innovations

Barry Love, MD, FRCPc, FSCAI

Barry Love, MD, FRCPc, FSCAI

Director, Congenital Cardiac Catheterization Laboratory

Patent Ductus Arteriosus

Before birth, the aorta and the pulmonary artery are connected by a blood vessel called the ductus arteriosus (DA). In fetal life, the DA serves to bypass blood away from the lungs and to the body, but typically, it closes within the first few days of life.

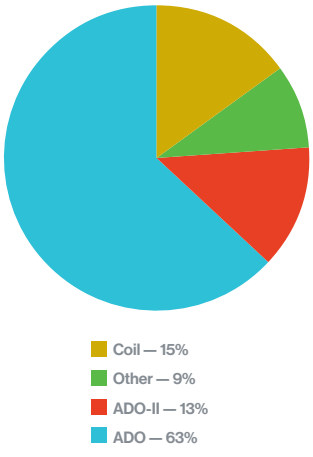
In about one in 2,000 term newborns, the DA remains open (patent). This condition, known as patent ductus arteriosus (PDA), allows high-pressure aortic blood to be directed to the pulmonary artery. A large PDA will allow a substantial left-to-right shunt and may lead to heart failure symptoms in the first weeks to months of life. Left untreated, pulmonary vascular damage may also occur leading to irreversible pulmonary hypertension. Large PDAs are treated in infancy to treat heart failure and prevent pulmonary vascular damage. If the PDA is moderate in size, the pressure is limited, but extra blood flow can lead to atrial arrhythmias and ventricular dysfunction from chronic left ventricular dilation later in life. PDAs of this size are typically addressed after a patient's first birthday.

Small PDAs do not pose a risk for pulmonary vascular damage or a significant dilation of the left atrium or left ventricle, but these PDAs can pose a risk for endarteritis stemming from the high-pressure jet aorta to the pulmonary artery that disrupts the normal endothelium. The risk of endarteritis with a PDA is about 1 percent per year. Since endarteritis from a PDA is a very difficult lesion to treat medically and can be life-threatening, small PDAs that are audible should be referred for closure.

Tiny PDAs that are found incidentally on echocardiogram in the absence of a murmur pose virtually no risk — even of endocarditis — and can generally be left alone. The exception to this is the small or tiny calcified PDA in a patient being referred for cardiac surgery. On cardiopulmonary bypass even a small PDA can divert from the systemic circulation and return a considerable amount of blood to the left atrium and left ventricle, obscuring the surgical field and preventing blood from reaching the end-organs. Surgical ligation of a calcified PDA is contraindicated due to its fragility and risk of rupture and uncontrollable bleeding. Patients with small, calcified PDAs should therefore have their PDAs closed using transcatheter methods prior to cardiac surgery.

Only recently have minimally invasive techniques become widespread for PDA closure. In 2004, the FDA approved the first device specifically designed for transcatheter PDA closure: the AMPLATZER™ Duct Occluder (ADO). This occluder is a mushroom-shaped, self-expanding device made with a nitinol wire mesh and polyester fabric to enhance occlusion. This device made it possible to close even large PDAs with excellent occlusion rates and minimal risk for embolization. For three years, Mount Sinai was a key implanting center for the FDA pivotal clinical trial with the second-highest U.S. enrollment of 25 centers.

Transcatheter device used in n=210 closures Mount Sinai experience 2003 - 2013



PATIENT: Erica Snell, 30-year-old woman

DIAGNOSIS: Small patent ductus arteriosus

TREATMENT: Closure with 5-4 ADO II occluder

"Dr. Love explained exactly what he was going to do, and the procedure went smoothly. I missed a few days of work and went back feeling just fine.

"I was almost 28 when I learned that I had a PDA. My doctor heard a 'baby' heart murmur, and asked me to see a cardiologist who diagnosed it with an echocardiogram. It had never bothered me, but the cardiologist said it could cause problems later in my life, such as infection, an enlarged heart and even heart failure."

"The cardiologist sent me to Dr. Love, who confirmed the diagnosis. He said that my PDA was small, and he wanted to wait a few months in anticipation of approval of a new, more appropriately sized closure device. When that device, the ADO II occluder, received FDA approval, his assistant Jamie called me with the news and I agreed to go in for the procedure.

"Dr. Love explained exactly what he was going to do, and the procedure went smoothly. I missed a few days of work and went back feeling just fine. I would almost call it a pleasant experience. I never knew I had a PDA, but now I have peace of mind knowing that it won't affect my future health. I'm grateful to Dr. Love and Mount Sinai."

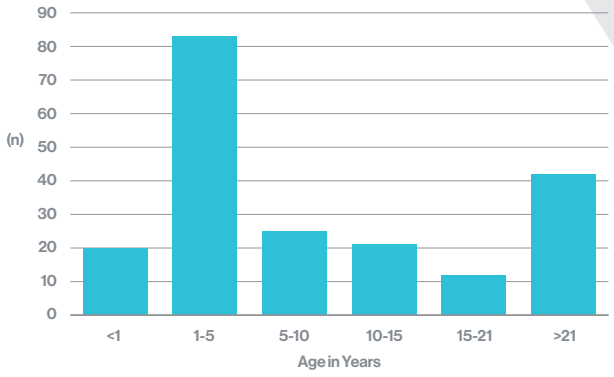
This past year saw the approval of a newer version – the ADO II. Like the original ADO, the ADO-II is also made of nitinol, but the wire is much finer and woven much tighter, obviating the need for the polyester fabric and allowing for delivery through a much smaller catheter. The symmetric design allows for delivery from either the pulmonary artery or aortic approach, making the device ideal for use in smaller PDAs. The delivery system allows for controlled delivery and repositioning if desired, unlike coils, which are committed once delivery has started.

Transcatheter PDA closure is generally performed as a same-day outpatient procedure. With modern PDA occluders, few patients beyond premature infants require surgical closure.

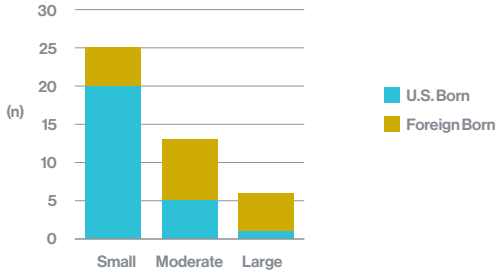
We recently examined our PDA closure data from the last 10 years at Mount Sinai. We performed 210 PDA closures. We found a 99.5 percent procedural success rate with a risk of minor complications of 1.3 percent.

Transcatheter closure of patent ductus arteriosus is a safe and effective treatment for patent ductus arteriosus from infancy through adulthood. Mount Sinai is a leader in the field of congenital heart disease interventions and is able to offer state-of-the-art therapies for these conditions.

Age at the Time of PDA Device Closure Mount Sinai Experience 2003 - 2013

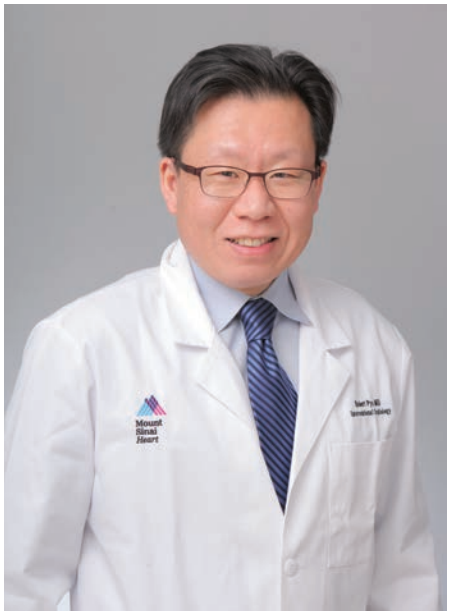


Size of PDAs Closed in Patients >21 years of Age at Mount Sinai vs. Country of Birth



Innovations

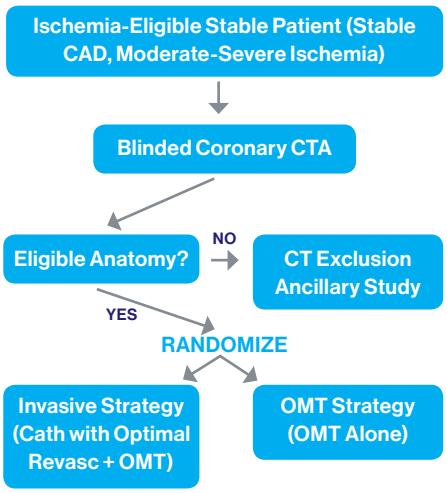
Robert Pyo, MD



Robert Pyo, MD

Assistant Professor of Medicine,
Cardiology and Radiology

ISCHEMIA Trial Design



Status of Revascularization in the Ischemic Patient

Ischemia in cardiovascular medicine is a state of imbalance between the demand of the myocardium for blood flow and the supply of blood flow. A common cause for this imbalance is atherosclerotic heart disease that narrows the lumen of the coronary artery. This imbalance constitutes the basic pathophysiology of ischemic heart disease.

In its acute form, narrowing can quickly progress to complete obstruction, leading to myocardial infarction (MI). Stable ischemic heart disease (SIHD) is the indolent form, and although patients with this disease can progress to MI, more often the presentation is symptoms of angina. In this case, the narrowing of the coronary arteries has occurred over many years.

Revascularization can address the basic pathophysiology of ischemic heart disease by bypassing or repairing the blockages. In the acute form of the disease, the optimal treatment for most cases is percutaneous revascularization with stent placement. In a minority of cases, the obstruction is so diffuse that surgical revascularization is indicated.

The choice of optimal treatment for SIHD is more complex. Simply restoring the balance between supply and demand mechanically may not be more effective than medical treatment. Contemporary data from trials such as COURAGE suggests that patients may do equally well with medical treatment as with revascularization with respect to prevention of death, MI and symptoms. Other studies, however, have supported the effectiveness of revascularization in certain subsets of patients. The SYNTAX and FREEDOM trials suggest that surgical revascularization can save the lives of patients with complex diffuse disease and in high-risk diabetic patients respectively. Additionally, data from the FAME trials suggests that invasive evaluation of ischemia may help identify patients that would benefit more with the addition of percutaneous revascularization on a background of optimal medical therapy for symptom relief.

Ongoing trials, many of which are associated with Mount Sinai, hope to clarify the landscape. The ISCHEMIA trial will evaluate the effectiveness of both surgical and percutaneous revascularization in patients with at least moderate ischemia. The YELLOW series of studies will investigate the effect of medical therapy in modifying the character of plaques. The results of these studies may have important implications in the use of novel technology to identify unstable plaques that may require aggressive therapy to prevent future cardiovascular events. The MACE study will help evaluate optimal percutaneous treatment of calcified plaques.

The approach to the ischemic patient should be evidence based, but the evidence is incomplete. In recognition of these facts, we strive to employ a heart team model, with experts from disciplines including non-invasive cardiology, interventional cardiology and cardiothoracic surgery working together to determine the best treatment for each patient.

Innovations
Jason Kovacic, MD, PhD

The Kovacic Laboratory

Dr. Jason Kovacic is jointly appointed at The Mount Sinai Hospital as a practicing interventional cardiologist and as head of the Kovacic Lab, which was founded in 2011 under the Icahn School of Medicine at Mount Sinai's Cardiovascular Research Center.

Under the leadership of Dr. Kovacic, research performed in this lab is aligned with Mount Sinai Heart's Cath Lab, including the basic science aspects of the YELLOW studies. Comprehensive basic and molecular studies are being conducted for the YELLOW II study in the Kovacic Lab, which complement the intracoronary artery imaging being performed by Dr. Annapoorna Kini in the Cath Lab. This synergy between the Kovacic Lab and the Cath Lab has already led to significant publications, and we are actively working to expand these scientific opportunities.

Funding for the Kovacic Lab comes from several sources, including the National Heart, Blood and Lung Institute and Foundation Leducq, under a TransAtlantic Network of Excellence. This Network of Excellence is made up of nine international laboratories working to unlock the governing mechanisms of stem cells in the heart with the goal of defining the mechanisms regulating and ultimately limiting the heart's repair ability.

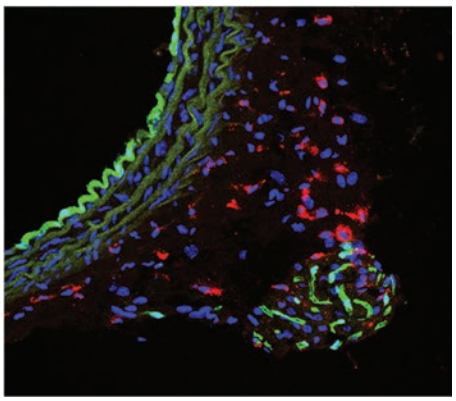
A core focus at our center is stem cell biology in the context of cardiovascular disease. It has been known that stem cells and progenitor cells play an important role in several vascular diseases, but the markers used to identify these cells were difficult to tag genetically, and some were not expressed in humans. A recently discovered molecular signature has provided us with a full toolkit that we can now use to study and understand the workings of these cells.

Another major focus of the Kovacic Lab is a disease called fibromuscular Dysplasia (FMD). Although it may present with problems such as heart attack or stroke, the cause of FMD is completely unknown. In fact, one of the only things we know about FMD is that there is probably a genetic problem, because 10 to 20 percent of patients have a family history of this disease. To try to better understand FMD, the Kovacic Lab has embarked on a major study called DEFINE-FMD. In collaboration with Dr. Jeffrey Olin of Mount Sinai who has a large clinic of these patients, we are collecting blood and a small skin biopsy from FMD patients. Patients' cells can be grown directly from this biopsy and studied for the causes and mechanisms of this disease. This important study began in early 2013 and we are aiming to collect fibroblast cells from up to 200 FMD patients.

In this fashion, working closely with Dr. Samin Sharma and Dr. Kini and capitalizing on the unique opportunities presented by the Catheterization Laboratory, the Kovacic Lab is striving to unlock some of the most important remaining questions underlining cardiovascular disease, the number one cause of mortality worldwide. Our long-term goal is to make meaningful inroads into the prevention and treatment of this disease.

Jason Kovacic, MD, PhD

Interventional Cardiologist and Head of the Kovacic Laboratory



This confocal laser microscope image taken in the Kovacic Lab shows the wall of an artery, with staining in green, blue and red to show some of the important different cell types that are involved and where these cells are located in the vessel.

Innovations

Jeffrey Bander, MD

Jeffrey Bander, MD
Assistant Professor of Medicine, Cardiology

Cardiology Outreach Network

In the outer boroughs of New York City as well as East Harlem, there are communities that are medically disadvantaged, for a variety of socioeconomic and cultural reasons. The residents of these communities often do not have information about or access to medical services, but they tend to be the people who need these services the most; they often have uncontrolled hypertension or cholesterol, or undiagnosed or untreated coronary or valvular disease that requires advanced therapies.

Mount Sinai Heart is reaching out to these underserved populations through the Cardiology Outreach Network, offering care that measures up to the same rigorous clinical standards that have long been the hallmark of our faculty practice. We are also taking advantage of the opportunity to intervene early with younger people who have uncontrolled risk factors before they have disease.

Our strategy is to identify a busy internal medicine practice in a targeted community, make connections with the doctors and rent space in that office. Scheduling and getting to appointments with specialists are often barriers to care in these communities, but now if they need to see a cardiologist they can do so right in their internist's or family practice physician's office.

Typically we rent two exam rooms in each practice, one for the imaging equipment that we bring with us, including electrocardiography, echocardiography and ankle brachial index machines, and one in which to meet with the patient. A team of cardiologist, nurse practitioner and imaging staff travels to each practice once every two weeks, seeing 20 to 30 patients over a very full day. We also conduct health screenings of blood pressure and cholesterol in these communities and offer health lectures, at mosques, synagogues and other local gathering places.

The mix of patients is quite diverse – a Muslim and an Orthodox Jew might be sitting next to each other in the waiting room. Members of the staff are often called upon to translate, in Spanish, Yiddish or Bengali. Another challenge is being culturally sensitive when delivering medical care. For example, both Muslims and Orthodox Jews must be examined by practitioners of their gender. But there are great rewards; we can and do have an enormous impact in communities that are underserved.

Today we have five established practices, two in North Williamsburg, Brooklyn, one in South Williamsburg, one in Crown Heights – in an enclave of Haitians, who tend to have uncontrolled hypertension – and one in East Harlem. The entire staff and the imaging machines all travel in a single SUV, and we leave no paper trail; all records are sent back to Mount Sinai electronically.

To sum up, through the Cardiology Outreach Network, Mount Sinai Heart is changing lives in the outer boroughs of New York City.

Innovations

Usman Baber, MD, MS

Contemporary Role of Platelet Function Testing in Percutaneous Coronary Intervention (PCI)

It has been well known for many years that platelets play a critical role in the pathogenesis of heart attacks. Until a decade ago, however, the only means of assessing platelet function was through time-consuming tests. Then assays were developed that could measure the activation level of platelets quickly and simply.

That launched many studies around the world to measure platelet activation levels of patients who had suffered heart attacks or undergone elective interventions. The conclusions of these reports were consistent: the higher the activation level, or aggregation, of the platelets, the higher the likelihood of future events.

Plavix (clopidogrel) is a platelet inhibitor, traditionally prescribed after a heart attack or PCI. Some hypothesized that patients with abnormally high levels of platelet activation might do better if they were prescribed more Plavix. The GRAVITAS trial, however, revealed no benefit with a double dose of Plavix. And the ARCTIC trial failed to show any improvement in outcomes using platelet-function monitoring to guide treatment in patients receiving drug-eluting stents (DES).

Although a high level of platelet activation is correlated with higher risk of future events, inhibiting them further does not appear to lower risk. Further, diabetics and those with renal failure also have elevated platelet levels. An elevated level appears to be a marker for people at high risk, but it should be a prognostic marker rather than playing a role in clinical decision making.

In an analogous situation, an aim of the ACCORD trial was to determine whether lowering hemoglobin A1c (an average of blood sugar control over a period of six to eight weeks) to less than 6 percent would reduce the risk for cardiovascular disease in patients with type 2 diabetes as compared to usual care, which was an A1c of between 7 percent and 8 percent. The number was driven down in the study, but without any measurable benefit to patients — in fact, it actually seemed to do some harm. Why? Diabetes is more complex than just glucose elevation, as with heart attack and platelet activation level.

Today, while platelet function testing remains a way to identify patients at higher risk, it does not seem to have a role in day-to-day clinical decision making. The research emphasis has shifted to studies comparing drugs when used to treat patients with severe heart attacks, including some that have been recently developed, for example, TRITON-TIMI 38, which compared Plavix to Effient (prasugrel), and PLATO, which compared Plavix to Brilinta (ticagrelor). In both examples, the new drugs were more efficacious than clopidogrel.

Usman Baber, MD, MS

Assistant Professor of Medicine, Cardiology

Innovations

Roxana Mehran, MD, FACC

Roxana Mehran, MD, FACC

Director, Interventional Cardiovascular Research and Clinical Trials

Impact of Post-DES DAPT Interruption

According to current guidelines, after placement of a drug-eluting stent (DES) in a coronary artery, a year of dual antiplatelet therapy (DAPT) is prescribed, a regimen of aspirin and an anticlotting agent, such as Plavix (clopidogrel). As stenting becomes increasingly more effective, some question if prolonged DAPT is still necessary.

These were the critical questions behind the PARIS Registry, which began in 2011 and followed 5,033 patients who had received stents. Patients were contacted and urged to be truthful about their adherence to DAPT without any risk of being penalized.

Two-year results of the PARIS Registry were reported in the fall of 2013 at the European Society of Cardiology, and the one-year results were borne out: Patients who discontinue DAPT with the guidance of their physicians actually have a significantly lower risk of cardiac events than those who continue DAPT for two years. It also found that when doctors ordered aspirin alone, there only was a bad outcome when there was disruption or interruption that was not guided by a physician.

Based on PARIS Registry data, we are designing studies that will examine antiplatelet regimens that are different and of shorter duration, with the goal of continued enhancement and improvement of care for our patients who have undergone stenting.

A related study in which we are enrolling patients here at Mount Sinai is the PIONEER AF-PCI trial; altogether 2,100 patients with atrial fibrillation and a stent will take part. These patients need Coumadin (anticoagulation therapy), as well as aspirin and Plavix (antiplatelet therapy), and prescribing the right regimen is a delicate operation; when you combine the three medications there is the possibility of bleeding issues, but without anticoagulation therapy there is the risk of stroke.

The primary purpose of the PIONEER study is to evaluate the safety of different Xeralto (rivaroxaban) treatment strategies and one Vitamin K antagonist (VKA) treatment strategy utilizing various combinations of DAPT or low-dose aspirin or a P2Y12 inhibitor (clopidogrel, prasugrel or ticagrelor). The trial subjects are being randomized into three arms. The primary endpoint will be clinically significant bleeding.

We aim to advance our stenting technology so that there is less need for these adjunct medications. In the meantime, we are trying to discover the optimum balance between bleeding risk and ischemic risk for our patients who undergo percutaneous coronary intervention (PCI), prescribing the best medications for the shortest length of time that is safe, to provide the best possible outcomes.

The medication regimen that is right for one patient is not right for another — every patient is different, with his or her own history and risk factors. How to determine each patient's "sweet spot" is an important focus of our research here at Mount Sinai and in the field of interventional cardiology in general.

Innovations

Melissa Mattimore ACNP-BC,
Chandra Bhim, AG-ACNP

Emphasis on Post-TAVR Management Contributes to Positive Outcomes

Transcatheter aortic valve replacement (TAVR) is a rapidly emerging treatment option for patients with severe aortic stenosis and a high or prohibitive risk for conventional surgical aortic valve replacement (SAVR). The Mount Sinai Hospital performed the first TAVR procedure with the Medtronic CoreValve system in the U.S. in December 2010. We are one of a few centers that offer both the Medtronic CoreValve and the Edwards SAPIEN device since 2012. One of the most important aspects of our TAVR program has been a focus on post-procedural care, including the development of in-depth post-procedure protocols.

Immediately after TAVR, patients are transferred to a specialized ICU where vital parameters including hemodynamics, AV conduction, neurologic status, ABG, fluid balance and renal status are monitored. Early extubation and mobilization are encouraged to prevent ventilator-associated complications and reduce ICU length of stay. Access sites are monitored closely, and a follow-up echocardiogram is performed within 24 hours to evaluate valve position and function. Antiplatelet therapy is prescribed after TAVR to reduce the risk of thrombotic or thromboembolic complications (if without contraindication). Patients who require oral anticoagulant therapy will be maintained on one antiplatelet agent to reduce bleeding risk.

The TAVR nurse practitioner (NP) and research coordinator evaluate patients daily and ensure that these protocols are instituted. Our dedicated consult team is familiar with this patient population, the TAVR procedure and potential complications. When indicated, the appropriate specialist participates with daily evaluation and medical management, and each TAVR patient sees our dedicated neurologist within 24 hours.

After invasive lines are removed, patients are transferred to a telemetry unit for continued monitoring and management. Patients will also be evaluated by our physical therapy team to help guide appropriate disposition upon discharge from the hospital setting. Patients are provided with clear discharge instructions and contact numbers. All post-TAVR patients will have follow-up with their cardiologist within one to two weeks of discharge and return to Mount Sinai for follow-up at 30 days. Following discharge, patients will be called within one week to evaluate their progress and medication adherence and to confirm follow-up appointments.

The development of clear and systematic post-procedure protocols has been a critical element of our TAVR program. It has contributed to the delivery of safe and effective care, and positive outcomes.

Research and Clinical Trials

In addition to unprecedented clinical success, Mount Sinai Cath Lab leads the field of Interventional Cardiology by conducting its own investigator-initiated trials and participating in numerous multicenter trials. The most important research developments of 2013 are the CoreValve TAVR and Tryton bifurcation side-branch 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 and progressive manner.

Top 10 Major Publications: Mount Sinai Cardiac Cath Lab

1. Creatine Kinase-MB Elevations After Coronary Intervention Correlates with Diffuse Atherosclerosis and Low-to-Medium-Level Elevation Has a Benign Clinical Course: Implication 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 percutaneous coronary intervention (PCI) and not associated with any higher mortality at 12 to 15 month follow-up. We also established through 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 coronary lesions but none of them is perfect. We invented a simplified bifurcation technique of placing two stents side by side with excellent short-term outcomes and lower restenosis (<5 percent) at 15 months of 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 occurs with bivalirudin use had a benign course compared to occurrence with heparin. This can be explained simply on the basis of short bivalirudin half-life.

4. Outcomes of Patients Discharged the Same Day 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 discharge of PCI patients (n=2,400) provided the system process for safe discharge of selected PCI patients with extremely low (<1 percent) major or minor cardiovascular and bleeding events at 30 days.

5. 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 appropriate use criteria (AUC) in determining the indications for PCI in stable CAD patients. It was reported that 14 percent of PCIs in NY State were inappropriate while for MSH it was remarkably low at 3.4 percent. We need to be vigilant and perform PCI only for the appropriately indicated patients.

6. Effect of Bivalirudin on Aortic Valve Intervention Outcomes (BRAVO) Study: A Two-Centre Registry Study Comparing Bivalirudin and Unfractionated Heparin in Balloon Aortic Valvuloplasty. Kini A, Yu J, Cohen M, Mehran R, Baber U, Sartori S, Vlachojannis G, Kovacic J, Pyo R, O'Neill B, Singh V, Jacobs E, Poludasu S, Moreno P, Kim M, Krishnan P, Sharma S, Dangas G. *EuroIntervention* 25:925, 2013.

Clinical Implications: This study reported for the first time the superiority of bivalirudin over unfractionated heparin during balloon aortic valvuloplasty in reducing major bleeding and vascular complications. Hence, a one-third to half-bolus dose of bivalirudin has now become standard during the BAV procedure.

7. Meta-Analysis of Everolimus-Eluting Versus Paclitaxel-Eluting Stents in Coronary Artery Disease: Final 3-Year Results of the SPIRIT Clinical Trials Program (Clinical Evaluation of the Xience V Everolimus Eluting Coronary Stent System in the Treatment of Patients With *De Novo* Native Coronary Artery Lesions). Dangas G, Serruys P, Kereiakes D, Hermiller J, Rizvi A, Newman W, Sudhir K, Smith R Jr, Cao S, Theodoropoulos K, Cutlip D, Lansky A, Stone G. *JACC Cardiovasc Interv* 6:914, 2013.

Clinical Implications: This study reported the long-term superiority of Xience everolimus-eluting DES vs. taxus paclitaxel-eluting DES in reducing restenosis and stent thrombosis.

8. Changes in Plaque Lipid Content After Short-Term Intensive Versus Standard Statin Therapy/The YELLOW Trial (Reduction in Yellow Plaque by Aggressive Lipid-Lowering Therapy). Kini A, Baber U, Kovacic J, Limaye A, Ziad A, Sweeny J, Maehara A, Mehran R, Dangas G, Mintz G, Fuster V, Narula J, Sharma S, Moreno P. *J Am Coll Cardiol* 62:21, 2013.

Clinical Implications: This is the first study to show a reduction in lipid content in the plaque as measured by near-infrared spectroscopy by high-dose statin in living patients. This observation has now led to two other trials in this field of lipid imaging.

9. Combined and Independent Impact of Diabetes Mellitus and Chronic Kidney Disease on Residual Platelet Reactivity. Baber U; Bander J; Karajgikar R, Yadav K, Hadi A, Theodoropoulos K, Gukathasan N, Roy S, Sayeneni S, Scott S, Kovacic J, Yu J, Sartori S, Mehran R, Uribarri J, Badimon J, Muntner P, Moreno P, Kini A, Sharma S, *Thromb Haemost 110:118, 2013.*

Clinical Implications: This study reported high residual platelet reactivity in diabetic patients suffering from chronic kidney disease. In these patients, there is high residual platelet reactivity post-PCI after clopidogrel administration. This may explain higher stent thrombosis rates in diabetic and renal patients.

10. Cessation of Dual Antiplatelet Treatment and Cardiac Events After Percutaneous Coronary Intervention (PARIS): Two-Year Results From a Prospective Observational Study. Mehran R, Baber U, Steg P, Ariti C, Weisz G, Witzenbichler B, Henry T, Kini A, Stuckey T, Cohen D, Berger P, Iakovou I, Dangas G, Waksman R, Antoniucci D, Sartori S, Krucoff M, Hermiller J, Shawl F, Gibson C, Chieffo A, Alu M, Moliterno D, Colombo A, Pocock S. *Lancet* 382: 1714, 2013.

Clinical Implications: This study showed that brief interruption of dual antiplatelet therapy by the physician did not increase the chances of stent thrombosis, while unsupervised DAPT discontinuation is associated with high stent thrombosis and MACE rates.

Top 10 Key Clinical Trials

Among the 42 clinical research trials being conducted at MSH Cath Lab, the following are the top 10 trials, which are likely to have an important 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
ABSORB Trial	A Clinical Evaluation of Absorb™ BVS, the everolimus-eluting bioabsorbable vascular scaffold, in the treatment of subjects with *de novo* native coronary artery lesions.	Abbott Vascular	A. Kini	2,200 (USA) 120 Centers	Closed Enrollment/ 41 subjects enrolled
SURTAVI Trial	The purpose of the study is to investigate the safety and efficacy of transcatheter aortic valve implantation (TAVI) in patients with severe, symptomatic aortic stenosis (AS) at intermediate surgical risk by randomizing patients to either surgical aortic valve replacement (SAVR) or TAVI with the Medtronic CoreValve System.	Medtronic	S. Sharma	2,500 (USA) 75 Centers	Ongoing/ 11 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	200 (USA) 50 Centers	Ongoing/ 463 subjects enrolled
AZ Brilinta Ad-Hoc PCI Trial	A randomized trial: open-label, multicenter, parallel group study to compare the platelet inhibition w/ VerifyNow assay of ticagrelor (Brilinta) vs. clopidogrel (Plavix) in troponin-negative ACS subjects undergoing ad-hoc PCI.	AstraZeneca	J. Sweeny	2,000 (USA) 220 Centers	Ongoing/ 14 subjects enrolled
YELLOW II Trial	Reduction in coronary yellow plaque, lipids and vascular inflammation by aggressive lipid lowering.	AstraZeneca	A. Kini	80 (USA) 1 Center	Ongoing/ 31 subjects enrolled

Study Title	Study Details	Sponsor	Principal Investigator(s)	Target Enrollment and Study Sites	Current Status/ Enrollment at MSH
ILLUMINATE Trial	Prospective, randomized, multicenter, single-blind study for the treatment of subjects presenting with *de novo* occluded/stenotic or reoccluded/restenotic lesions of the superficial femoral or popliteal arteries using a paclitaxel-coated or bare percutaneous transluminal angioplasty balloon catheter.	CV Ingenuity Corporation	J. Wiley	360 (USA) 45 Centers	Ongoing/ 18 subjects enrolled
MACE Trial	Multicenter prospective study to evaluate outcomes of moderate to severely calcified coronary lesions.	CSI	S. Sharma	500 (USA) 20 Centers	Ongoing/ 17 subjects enrolled
COAPT Trial	The purpose of the cardiovascular outcomes assessment of the MitraClip percutaneous therapy for heart failure patients with functional mitral regurgitation trial is to confirm the safety and effectiveness of the MitraClip system for the treatment of moderate-to-severe or severe functional mitral regurgitation (FMR) in symptomatic heart failure subjects.	Abbott Vascular	S. Sharma	430 (USA) 52 Centers	Ongoing/ 1 subject enrolled
Renal Guard Trial	A study to evaluate the safety and efficiency of the RenalGuard® system when compared with the standard of care in the prevention of contrast-Induced nephropathy (CIN) in the setting of a catheterization laboratory.	PLC Medical Systems	G. Dangas	326 (USA) 20 Centers	Ongoing/ 17 subjects enrolled
EXCEL Trial	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	A. Kini	2,600 (Global) 165 Centers Trial stopped enrollment after 1800 cases	Ongoing/ 29 subjects enrolled; 18 randomized

Full Time Senior Faculty

Clinical Interests:

Coronary Artery Disease
Interventional Cardiology
Valvular Intervention

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

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: The Mount Sinai Hospital, NY

Dr. Samin K. Sharma is well known for complex coronary interventions, performing over 1,500 each year with an extremely low complication rate. According to New York State DOH reports, he had the highest angioplasty success rate among interventional cardiologists in New York State from 1994 to 2003 and 2007 to 2008, a remarkable feat considering the complexity of cases referred. Dr. Sharma has authored more than 150 articles, 300 abstracts and 12 book chapters and was editor of *Cardiology Clinic* (December 2006 and February 2010) issues and *Interventional Cardiology Clinic* (2012-2014). His publications focus primarily on innovative procedural techniques to improve interventional success and reduce complication rates. He has been dubbed "master of the Rotablator" and is regularly featured on national and local TV and in newspapers and magazines including *Newsday, Newsweek, New York Times, New York Post, Forbes, Wall Street Journal, New York Daily News, Washington Post, New York* magazine*, India Abroad* and *India Today*. 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, many interventionalists learn from Dr. Sharma's masterful teaching to become safe operators.

Dr. Sharma has received numerous awards for excellence, including the 2011 Ellis Island Medal of Honor, the 2011 American Heart Association Achievement in Cardiovascular Science & Medicine Award, the 2011 Physician of the Year award from the American Association of Physicians of Indian Origin (AAPI), 2003-2007 and 2009-2013 Best Doctors, 2008-2013 Super Doctors, 2007 Jacobi Medallion Award and the 2007 Physician of the Year Award at The Mount Sinai Hospital. New York Governor George Pataki presented Dr. Sharma with the Governor's Excellence Award in 2006. Dr. Sharma has had the privilege of performing invasive procedures on heads of state and has served on New York State's Cardiac Advisory Board since 2004. He became an attending at The Mount Sinai Hospital in 1990, and he is currently the Director of Interventional Cardiology (since 1996), Director of Clinical Cardiology (2011), Dean of International Clinical Affiliations (2011), President of the Mount Sinai Heart Network (2011) and Zena and Michael A. Wiener Professor of Medicine, Cardiology (2002).

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Annapoorna S. Kini, MD, MRCP, FACC

Director Cardiac Catheterization Laboratory
Professor Medicine, Cardiology
Director, Interventional Cardiology Fellowship

Education and Training

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

Dr. Kini was newly appointed director of the Cardiac Cath Lab in 2011. She performs over 1,000 coronary interventions annually (the highest number by a female interventionalist in the United States) with an extremely low complication rate of <0.3 percent. According to New York State Department of Health Report for 2004-2006, 2005-2007 and 2009-2011, Dr. Kini received the ** status for percutaneous coronary intervention (PCI) safety amongst >400 other Interventionalists. She is highly regarded for performing complex coronary interventions, especially in chronic total occlusions for patients with advanced heart disease, with the utmost safety and excellent long-term results. She is also a national expert in various intracoronary imaging modalities such as optical coherence tomography and near-infrared spectroscopy. Dr. Kini also specializes in the noncoronary interventions of mitral and aortic balloon valvuloplasty, alcohol septal ablation for obstructive hypertrophic cardiomyopathy 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 projects in coronary imaging are currently under way, including the YELLOW Trial and various YELLOW substudies. Dr. Kini is also the lead enroller for several multicenter national clinical studies, including the Tryton Side Branch Stent study, Color Registry and the Expert CTO trial.

In 2011, Dr. Kini received the "Rock Star of Science" award from the American Heart Association. She is the recipient of 2011 Dean's Award for Excellence in Clinical Medicine at the The Mount Sinai Hospital for unprecedented clinical skills. She was listed as a *New York Times Magazine* Super Doctor every year since 2009.

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Clinical Interests:

Intravascular Imaging
Interventional Cardiology: CTO
Hypertrophic Cardiomyopathy

Clinical Interests:
Coronary Artery Disease
Interventional Cardiology
Plaque Imaging

Pedro R. Moreno, MD, FACC

Professor of Medicine, Cardiology
Director, Translational Research, Cardiac Catheterization Laboratory

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, intraplaque hemorrhage, the role of macrophages and tissue factor in patients with acute coronary syndromes has greatly enhanced the body of knowledge in this emerging area of cardiology. These findings provided the rationale for revolutionary state-of-the-art therapies including anti-inflammatory and anti-proliferative drug-eluting stents used worldwide. His research using near-infrared spectroscopy was pivotal in the development of the now-ubiquitous LipiScan catheter. He is board certified in cardiology and interventional cardiology and committed to teaching around the world, with professorships in multiple international organizations. Dr. Moreno works to improve cardiovascular health in the Latino community of New York, with extensive clinical work and educational media interviews. As an interventionalist, Dr. Moreno preforms more then 500 procedures with less then 1 percent major complications. For this, Dr. Moreno was award the two-star safety award by the New York State Department of Health in 2013.

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Clinical Interests:
Interventional Cardiology
Peripheral Artery Disease
Endovascular Intervention

Prakash Krishnan, MD, FACC

Assistant Professor of Medicine, Cardiology
Director of Endovascular Services

Education and Training

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

Dr. Prakash Krishnan is co-director of the annual Live Symposium of Complex Coronary & Vascular Cases, an Icahn School of Medicine at Mount Sinai and Cardiovascular Institute-supported program; and director of Mount Sinai's Peripheral Interventions Live webcast. Dr. Krishnan's expertise includes nonsurgical treatment of coronary and peripheral vascular diseases including coronary stents, peripheral vascular angioplasty and stents, atherectomy, carotid stents, renal stents, renal denervation, complex venous disease intervention, as well as atrial septal defect (ASD) and patent foramen ovale (PFO) closure. He performs more than 600 coronary and peripheral interventions annually. Dr. Krishnan is a patient advocate and an educator. Over the years he has built a robust community-based outreach program that serves a vast population of patients with complex coronary and peripheral arterial diseases at offices in all five boroughs. He has been on staff at The Mount Sinai Hospital since 2004.

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George Dangas, MD, PhD, FACC, FSCAI

Professor of Medicine, Cardiology
Professor of Surgery, Vascular
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: The Mount Sinai Hospital
- Fellowship, Interventional Cardiology: The Mount Sinai Hospital

Clinical Interests:

Interventional Cardiology

Valvular Heart Disease

Endovascular Intervention

Dr. George Dangas performs a wide spectrum of complex cardiovascular interventional procedures to treat coronary and valvular heart disease, aortic, carotid and peripheral arterial disease and resistant hypertension. Dr. Dangas is a leading authority in the performance of nonsurgical cardiac and vascular interventions and in the development of innovative approaches to treat complex problems across many specialties. He is currently a trustee of the American College of Cardiology and editor-in-chief of *CardioSource WorldNews Interventions* journal and has been chair of the Interventional Scientific Council and a trustee of the Society for Cardiovascular Angiography & Interventions. He is co-director of the annual conferences Transcatheter Cardiovascular Therapeutics and Interventional Fellows' Courses in the USA and Europe and a key faculty and program committee member for multiple international conferences including the ACCi2 Summit, ACCIS, AHA and SCAI for many years. Dr. Dangas is the Director of Academic Affairs at the Cardiovascular Research Foundation.

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

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

Education and Training

- MD, St. George's University School of Medicine, Grenada, WI
- Residency, Internal Medicine: University of Connecticut
- Fellowship, Cardiovascular Disease: The Mount Sinai Hospital
- Fellowship, Interventional Cardiology: The Mount Sinai Hospital

Clinical Interests:

Restenosis Prevention

Contrast-Induced Acute Kidney Injury (AKI)

Cardiovascular Disease in Women

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

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Sean P. Pinney, MD, FACC

Associate Professor of Medicine, Cardiology
Director, Advanced Heart Failure and Cardiac Transplant Program

Education and Training

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

Clinical Interests:

Cardiac Catheterization
Cardiac Transplantation
Heart Failure

Dr. Sean Pinney is a well-known cardiologist specializing in the management of patients with advanced heart failure. Together with Cardiothoracic Surgeon 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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Barry A. Love, MD, FRCPc

Assistant Professor of Pediatrics and Medicine
Director, Congenital Cardiac Catheterization Laboratory

Education and Training

- MD: University of Western Ontario
- Residency, Pediatrics: McGill University Medical Center
- Fellowship: Children's Hospital Boston

Clinical Interests:

Pediatric Catheterization and Intervention
Adult Congenital Heart Disease

Dr. Barry Love is Director of the Congenital Cardiac Catheterization Laboratory at Mount Sinai Heart. Dr. Love holds a joint appointment in both the Department of Pediatrics and the Department of Medicine and is one of only a few physicians who perform interventional procedures on patients with congenital heart disease from infancy through adulthood. He has been a pioneer in extending many of the techniques used in the treatment of congenital heart disease to acquired heart lesions in adults such as perivalvular leaks and post-infarction ventricular septal defects. He has been recognized by Castle Connolly as one of America's Top Doctors for 2009-2012 and is listed as a *New York Times Magazine* Super Doctor for 2008 to 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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Full-Time Affiliate Faculty

Javed Suleman, MD

Associate Clinical Professor of Medicine, Cardiology

Education and Training

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

Clinical Interests: Clinical Cardiology, Cardiac Catheterization, Coronary Intervention, Primary PCI, Global Cardiac Disease Initiative

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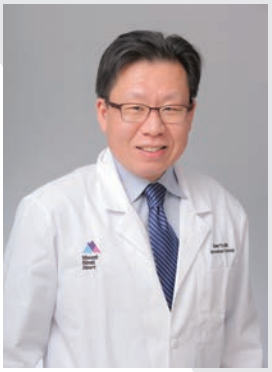
Robert Pyo, MD



Assistant Professor of Medicine, Cardiology and Radiology

Education and Training

- MD: University of Illinois
- Residency, Internal Medicine: Elmhurst Hospital
- Fellowship, Cardiology: The Mount Sinai Hospital, NY
- Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Clinical Interests: Clinical Cardiology, Cardiac Catheterization, Coronary Interventions, Peripheral Interventions, Percutaneous Treatment of Valve Disease

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José M. Wiley, MD

Assistant Professor Medicine, Cardiology and Radiology
Associate Director, Endovascular Intervention

Education and Training

- MD: Universidad Central del Caribe, Bayamon, Puerto Rico
- Residency, Internal Medicine: Tulane University School of Medicine
- Fellowship, Cardiology: Tulane University School of Medicine
- Fellowship, Interventional Cardiology: Ochsner Clinic Foundation

Clinical Interests: Interventional Cardiology, Cardiac Catheterization, Endovascular Intervention, Structural Heart Disease

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Joseph M. Sweeny, MD

Assistant Professor of Medicine, Cardiology

Education and Training

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

Clinical Interests: Acute Myocardial Infarction, Fellows Education, Coronary Intervention

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Ajith Nair, MD

Assistant Professor of Medicine, Cardiology

Education and Training

- MD: University of Texas, Southwestern, Dallas, TX
- Residency: The Mount Sinai Hospital, NY
- Fellowship: The Mount Sinai Hospital, NY

Clinical Interests: Pulmonary Hypertension, Advanced Heart Failure & Mechanical Support, Cardiac Transplantation

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Atul M. Limaye, MD, MRCP

Assistant Professor of Medicine, Cardiology

Education and Training

- MBBS: MAMC, University of Delhi, India
- Residency: Bronx Lebanon Hospital Center, NY
- Fellowship, Noninvasive Cardiology: Brigham & Women's Hospital, Boston
- Fellowship, Cardiology: Montefiore Medical Center, NY
- Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Clinical Interests: Clinical Cardiology, Coronary Interventions, Peripheral Interventions

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Jason Kovacic, MD, PhD

Assistant Professor of Medicine, Cardiology

Education and Training

- MD: University of Melbourne, Australia
- PhD: Victor Chang Cardiac Research Institute through University of New South Wales, Australia
- Residency, Internal Medicine: Prince of Wales Hospital, Sydney, Australia
- Fellowship, Cardiology: St. Vincent's Hospital, Sydney, Australia
- Fellowship, Vascular Biology: National Heart Lung and Blood Institute, National Institutes of Health
- Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Clinical Interests: Coronary Interventions, Clinical Cardiology, Vascular Biology, Atherosclerosis

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Sameet Palkhiwala, MD

Assistant Clinical Professor of Medicine, Cardiology
Director of Cardiology, The Mount Sinai Hospital of Queens

Education and Training

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

Clinical Interests: Clinical Cardiology, Endovascular Interventions, Coronary Interventions

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Usman Baber, MD, MS

Assistant Professor of Medicine, Cardiology

Education and Training

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

Clinical Interests: Coronary Interventions, High-Risk Populations, Cardiorenal Physiology

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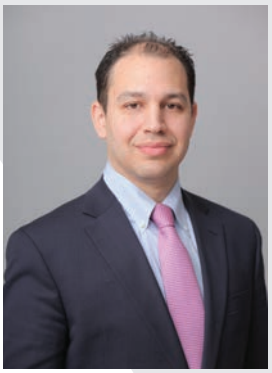
Jeffrey Bander, MD



Assistant Professor of Medicine, Cardiology

Education and Training

- MD: Harvard Medical School
- Residency: Columbia Presbyterian Medical Center, NY
- Fellowship, Cardiology: The Mount Sinai Hospital, NY
- Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Clinical Interests: Clinical Cardiology, Cardiac Catheterization, Coronary Interventions

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Michael Alan G. Sicat, MD

Assistant Professor of Medicine, Cardiology

Education and Training

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

Clinical Interests: Clinical Cardiology, Cardiac Catheterization

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Daniel Soffer, MD

Associate Professor of the Practice of Medicine, Cardiology
Co-Director, Carotid Endovascular Services

Education and Training

- MD: Ben Gurion University of the Negev, Beer Sheva, Israel
- Residency; Internal Medicine: Lenox Hill Hospital, NY
- Fellowship, Cardiology, Clinical Cardiology: Lenox Hill Hospital, NY
- Fellowship, Interventional Cardiology and Endovascular Interventions: William Beaumont Hospital, Royal Oak, MI

Clinical Interests: Interventional Cardiology, Structural Heart, Endovascular and Carotid Interventions, Valvuloplasty

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Jagat Narula, MD, PhD

Philip J. and Harriet L. Goodhart Professor of Medicine
Associate Dean for Global Health
Director, Cardiovascular Imaging Program
Director of Operations, Mount Sinai Heart Network

Education and Training

- MD: SMS Medical School, India
- Fellowship [Cardiology, Heart Failure & Transplantation, Nuclear Cardiology]: Massachusetts General Hospital and Harvard Medical School

Clinical Interests: Noninvasive and Invasive Cardiovascular Imaging

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Partho P. Sengupta, MD

Associate Professor of Medicine Cardiology
Director of Ultrasound Research, Medicine & Cardiology

Education and Training

- MD: Government Medical College, Nagpur, India
- Residency: Mayo Clinic, Rochester, MN
- Fellowship, Cardiology: Mayo Clinic, Scottsdale, AZ
- Fellowship, Advanced Fellowship in Echocardiography: Mayo Brothers Distinguished
- Fellowship: Mayo Clinic School of Medicine, Rochester, MN

Clinical Interests: Structural Heart Imaging, Cardiac Muscle and Fluid Mechanics; Automated Imaging Algorithms

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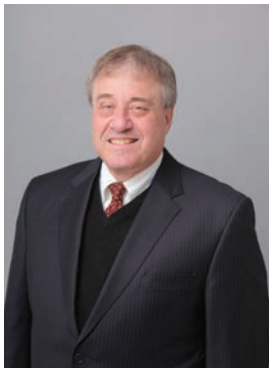

Michael J. Domanski, MD

Professor of Medicine
Director, Heart Failure Research
Director, Inpatient Heart Failure Program

Education and Training

- MD: University of Maryland School of Medicine
- Residency, Internal Medicine: Pennsylvania State University of School of Medicine
- Fellowship, Cardiology: Vanderbilt University School of Medicine

Clinical Interests: Clinical Cardiology, Cardiac Catheterization, Coronary Interventions

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Voluntary/Part-Time Faculty

José Meller, MD

Clinical Professor of Medicine, Cardiology

Education and Training

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

Clinical Interests: Clinical Cardiology, Fellows Education, Cardiac Catheterization

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Johnny Lee, MD

Assistant Clinical Professor of Medicine, Cardiology

Education and Training

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

Clinical Interests: Clinical Cardiology, Noninvasive Cardiology, Coronary Interventions

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Paul C. Lee, MD

Associate Professor of Medicine, Cardiology

Education and Training

- MD: University of Minnesota
- Residency, Internal Medicine: The Mount Sinai Hospital, NY
- Fellowship, Cardiology: The Mount Sinai Hospital
- Fellowship, Clinical Heart Failure and Molecular Cardiology: University of Toronto

Clinical Interests: Clinical Cardiology, Biostatistics, Interventional Cardiology

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Srinivas Kesanakurthy, MD

Assistant Clinical Professor of Medicine, Cardiology

Education and Training

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

Clinical Interests: Clinical Cardiology, Cardiac Catheterization, Coronary Interventions

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Robert A. Zaloom, MD

Assistant Clinical Professor of Medicine, Cardiology

Education and Training

- MD: Ross University School of Medicine
- Residency, Internal Medicine: Lutheran Medical Center
- Fellowship, Cardiology: SUNY Downstate Medical Center, NY

Clinical Interests: Clinical Cardiology, Echocardiography, Cardiac Catheterization

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George Fernaine, MD

Assistant Clinical Professor of Medicine, Cardiology

Education and Training

- MD: SUNY Downstate Medical Center, NY
- Residency, Internal Medicine: St. Vincent's Hospital
- Fellowship, Cardiology: St. Vincent's Hospital
- Fellowship, Interventional Cardiology: Lenox Hill Hospital, NY

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

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Farah E. Atallah-Lajam, MD

Associate Clinical Professor of Medicine, Cardiology

Education and Training

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

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

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William J. Schwartz, MD

Assistant Clinical Professor of Medicine, Cardiology

Education and Training

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

Clinical Interests: Clinical Cardiology, Noninvasive Cardiology, Cardiac Catheterization

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Choudhury M. Hasan, MD

Assistant Clinical Professor of Medicine, Cardiology

Education and Training

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

Clinical Interests: Cardiac Catheterization, Coronary Interventions, Echocardiography

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Timothy G. Jayasundera, MD

Clinical Instructor of Medicine, Cardiology

Education and Training

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

Clinical Interests: Interventional Cardiology, Aspirin and Clopidogrel Resistance, Acute Coronary Syndromes, Peripheral Arterial Disease (PAD)

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Niranjan K. Mittal, MD

Clinical Instructor of Medicine, Cardiology

Education and Training

- MBBS: Government Medical College, Patiala, India
- Residency, Internal Medicine: Jamaica Hospital, NY
- Fellowship, Cardiology: Brooklyn Hospital Center
- Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Clinical Interests: Cardiac Imaging, Interventional Cardiology

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Anuj Shah, MD

Assistant Professor Medicine, Cardiology
Education and Training

Education and Training

- MD: Gujarat University, India
- Residency: Internal Medicine: University of Connecticut
- Fellowship, Cardiovascular Disease: Hartford Hospital, University of Connecticut
- Fellowship, Interventional Cardiology: The Mount Sinai Hospital

Clinical Interests: Interventional Cardiology, Peripheral Vascular Disease and Interventions

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Asim Hameedi, MD

Clinical Instructor of Medicine, Cardiology

Education and Training

- MD: SUNY Downstate Medical Center, NY
- Residency: Albert Einstein College of Medicine/Montefiore Medical Center, NY
- Fellowship, Cardiology: SUNY Downstate Medical Center, NY
- Fellowship, Interventional Cardiology: SUNY Downstate Medical Center, NY

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Vinod Patel, MD

Education and Training

- MD: Saurastra University, M.P. Shah Medical College, Gujaret, India
- Residency, Internal Medicine: Resurrection Hospitals/Stritch School of Medicine, Loyola University, Chicago
- Fellowship, Cardiology: University of South Florida
- Fellowship, Cardiology Imaging: University of Alabama at Birmingham
- Fellowship, Interventional Cardiology: The Mount Sinai Hospital, NY

Clinical Interests: New Device Technology Development, Noninvasive Cardiology, Cardiac Catheterization, Cardiac Interventions, Peripheral Vascular Interventions

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Dimitrios Bliagos, MD

Assistant Professor of Medicine, Cardiology

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

Clinical Interests: Clinical Cardiology, Coronary Intervention, Endovascular Intervention

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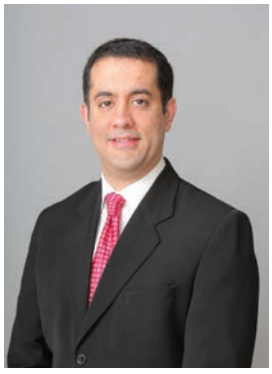

Vishal Kapur, MD

Assistant Professor of Medicine, Cardiology

Education and Training

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

Clinical Interests: Coronary Interventions, Peripheral Interventions, Non-Invasive Vascular Medicine, Clinical Cardiology

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Ankur Shah, MD

Assistant Professor of Medicine, Cardiology

Education and Training

- MBBS: SMT: NHL Municipal Medical College, Ahmedabad, India
- Residency: Allegheny General Hospital, Pittsburgh, PA
- Fellowship, Non-Invasive Cardiology: Allegheny General Hospital, Pittsburgh, PA
- Fellowship, Interventional Cardiology: Hahnemann University Hospital, Philadelphia, PA

Clinical Interests: Clinical Cardiology, Coronary Interventions, Peripheral Interventions

Phone: 412-491-7611 **E-mail: ankurshah78@gmail.com**

Lynne Glasser, MD

Assistant Professor of Medicine, Cardiology
Director, Interventional Inpatient Service

Education and Training

- MD: SUNY Downstate Medical Center, NY
- Residency, Internal Medicine: New York University Medical Center
- Fellowship, Cardiology: Manhattan Veterans Administration Medical Center

Clinical Interests: Clinical Cardiology, Preventive Cardiology

Since joining The Mount Sinai Hospital in November 2008, Dr. Glasser has been playing an important role in the treatment and management of interventional patients, before and after the procedure.

Phone: 212-241-4521 **E-mail: lynne.glasser@mountsinai.org**

Beth Oliver, RN

Vice President of Cardiac Services, Mount Sinai Health System

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 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.

Phone: 212-241-0796 **E-mail: beth.oliver@mountsinai.org**

Rosario Marasigan, RN

Clinical Nurse Manager

Education and Training

- BS: Nursing: Philippine Women's University

Rosario Marasigan has been the clinical nurse manager since 2006. In this role she efficiently and effectively manages a unit with a complex staff of more than 167 health professionals.

Rosario was an excellent clinical and charge nurse for 16 years prior to becoming the manager. Being a nursing instructor in the past makes her a great teacher at the bedside and a role model for our new nurses in the Cardiac Catheterization Laboratory. She is a certified critical care nurse and an active member of AACN since 1990.

Phone: 212-241-1835 **E-mail: rosario.marasigan@mountsinai.org**

Gregory Gojkovich

Operations Manager

Education and Training

- AA Degree, Moorpark College, California

Greg Gojkovich joined the Mount Sinai Cath Lab in January 1987. In 1992, he accepted a cath lab operational manager position at Beth Israel Medical Center, New York, NY. He returned to Mount Sinai in 2001.

Phone: 212-241-1548 **E-mail: gregory.gojkovich@mssm.edu**

Nurse Practitioner Team

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


Antonietta Tolentino


Dominique Sicile


Gloria Manzanilla


Haydee Garcia


Jenifer Del Campo


Kevin Williams


Kristelle Pulido


Leticia Jakasal


Melissa Mattimore


Nerissa Plondaya


Rheoneil Lascano


Sandie Ronain


Supawadee Pitakmongkolkul


Tanya Sullivan


Taurean Harrilal (PA)


Tia Coleman


Vivian Lau


Chondra Bhim

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.


Antony Innasimuthu, MD


Mayur Lakhani, MD


Surabhi Madhwal, MD


Sadik Panwar, MD


Rikesh Patel, MD


Anitha Rajamanickam, MD


Ravinder Rao, MD


Rahul Sawant, MD


Nagendra Senguptten, MD


Faramarz Tehrani, MD


Christopher Varughese, MD


Karthik Gujja, 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) Arjun Bhat, Sandeep Basnet, Omarys Herasme, Miguel Vasquez, Michael Fusilero, Kleanthis Theodoropoulos, Eyal Levy, Yuliya Vengrenyuk, Asif Adam, Omar Meelu, Arthur Tarricone

Supporting Staff

Back Row: Shulandia Avila, StacyAnn Reid, Maria Diaz, Kelly Worrell, Debra Bradley

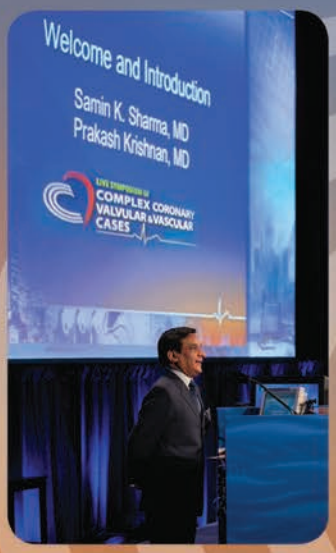
Front Row: Pearl Tongson, Kimberley Kostiw, Maria Directo, Era Zuberko

LIVE SYMPOSIUM OF 17TH ANNUAL

COMPLEX CORONARY VALVULAR & VASCULAR CASES

SPECIAL FOCUS ON CALCIFIED, BIFURCATION & TOTAL OCCLUSION LESIONS

Tuesday, June 10th	|	NURSE / TECHNOLOGIST SYMPOSIUM INTERVENTIONAL CARDIOLOGY FELLOWS COURSE ENDOVASCULAR FELLOWS COURSE
Wednesday, June 11th	|	ENDOVASCULAR SYMPOSIUM *Iliac, Femoral, Renal, Carotid*
Thursday, June 12th	|	COMPLEX CORONARY SYMPOSIUM *Unprotected Left Main, Calcified, Bifurcation and Chronic Total Occlusion*
Friday, June 13th	|	STRUCTURAL HEART / CORONARY SYMPOSIUM *TAVR, Valvuloplasty, Septal Ablation, PFO/ASD Closure*



Highlights

- Complex High-Risk Coronary Cases
- Unprotected Left Main
- Chronic Total Occlusion
- Intravascular Brachytherapy
- Alcohol Septal Ablation
- Aortic and Mitral Valvuloplasty
- Percutaneous Valve Replacement and Repair
- Endovascular Intervention of Calcified Lesions, Total Occlusions and Tibial Disease
- PFO/ASD Closure

CORONARY SYMPOSIUM DIRECTORS
Samin K. Sharma, MD, FACC, FSCAI
Annapoorna S. Kini, MD, MRCP, FACC

CORONARY SYMPOSIUM CO-DIRECTORS
Pedro R. Moreno, MD, FACC
George Dangas, MD, PhD, FACC, FSCAI
Roxana Mehran, MD, FACC, FSCAI
Robert Pyo, MD
Joseph M. Sweeny, MD
Jagat Narula, MD, PhD, MACC, FRCP

STRUCTURAL HEART DISEASE DIRECTORS
Samin K. Sharma, MD, FACC, FSCAI
Annapoorna S. Kini, MD, MRCP, FACC

STRUCTURAL HEART DISEASE CO-DIRECTORS
George Dangas, MD, PhD, FACC, FSCAI
Jason Kovacic, MD, PhD, FACC, FSCAI
Barry Love, MD, FRCPc
Partho P. Sengupta, MD, DM, FACC, FASE

ENDOVASCULAR SYMPOSIUM DIRECTORS
Prakash Krishnan, MD, FACC
Peter L. Faries, MD, FACS

ENDOVASCULAR SYMPOSIUM CO-DIRECTORS
J. Michael Bacharach, MD, FACC, FSCAI
Jose M. Wiley, MD, FACC, FSCAI
Jeffrey W. Olin, DO, FACP, FACC

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

Mount Sinai Heart

SCAI The Society for Cardiovascular Angiography and Interventions

www.cccsymposium.org

CCC Live Cases

Complex Coronary Cases

Viewed in 131 Countries

Afghanistan
Albania
Algeria
Argentina
Armenia
Aruba
Australia
Austria
Azerbaijan
Bahamas
Bahrain
Bangladesh
Barbados
Belarus
Belgium
Bolivia
Bosnia and Herzegovina
Botswana
Brazil
Bulgaria
Cambodia
Canada
Chile
China
Colombia
Costa Rica
Croatia
Curacao
Cyprus
Czech Republic
Denmark
Dominica
Dominican Republic
Ecuador
Egypt
El Salvador
Estonia
Finland
France
Georgia
Germany
Ghana
Greece
Grenada
Guadeloupe
Guam
Guatemala
Guernsey
Honduras
Hong Kong
Hungary
Iceland
India
Indonesia
Iran
Iraq
Ireland
Israel
Italy
Jamaica
Japan
Jordan
Kazakhstan
Kenya
Kosovo
Kuwait
Kyrgyzstan
Latvia
Lebanon
Libya
Lithuania
Macedonia (FYROM)
Malaysia
Mauritius
Mexico
Moldova
Montenegro
Morocco
Myanmar (Burma)
Namibia
Nepal
Netherlands
New Zealand
Nicaragua
Nigeria
Norway
Oman
Pakistan
Palestine
Panama
Peru
Philippines
Poland
Portugal
Puerto Rico
Qatar
Reunion
Romania
Russia
Saint Lucia
Saudi Arabia
Serbia
Singapore
Slovakia
Slovenia
South Africa
South Korea
Spain
Sri Lanka
Sudan
Sweden
Switzerland
Syria
Taiwan
Thailand
Trinidad and Tobago
Tunisia
Turkey
Uganda
Ukraine
United Arab Emirates
United Kingdom
United States
Uruguay
Venezuela
Vietnam
Yemen
Zimbabwe

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

2014 Web Conference Schedule

8:00 TO 9:00 AM

June 17, 2014

July 15, 2014

August 19, 2014

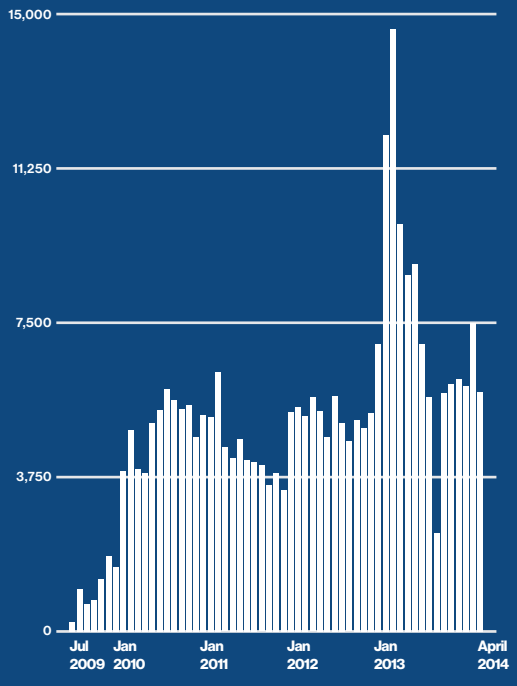
Sept 16, 2014

Oct 21, 2014

Nov 18, 2014

Dec 16, 2014

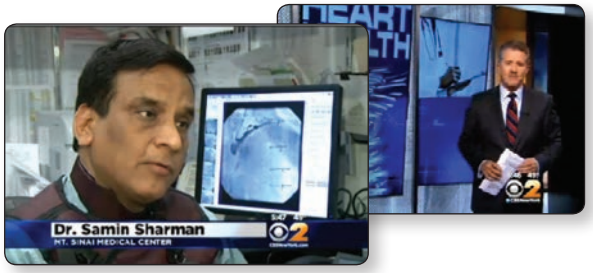
Total PageViews 291,207



Cardiac Catheterization Laboratory Achievements

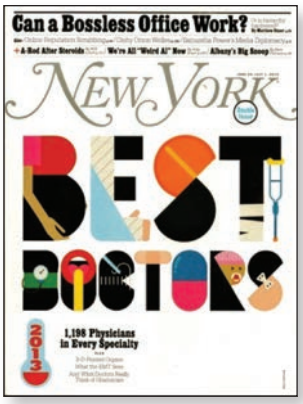
CBS NY:

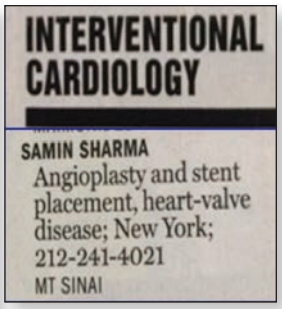
Dr. Samin K. Sharma talks to Max Gomez from CBS 2 New York about Orbital Atherectomy



NY Magazine:

Dr. Samin K Sharma listed as Best Doctor from 2006-2008 and 2011-2013





New York Times:

Dr. Samin K. Sharma listed as Top Doctor by Castle Connolly

Super Doctors:

Dr. Samin K. Sharma and Dr. Annapoorna S. Kini were listed as Super Doctors in 2013

ABC 7:

Dr. Annapoorna S. Kini was interviewed by ABC 7 about Absorbable Stents

Telemundo:

Dr. Pedro Moreno featured on Telemundo

USA Today:

Dr. George Dangas was interviewed by USA Today about Heart Health Guidelines

Mount Sinai Heart Directory

Area	Telephone
Mount Sinai Heart Director	212-241-7911
Cardiac Nursing	212-241-3483
Cardiac Rehab Program	212-241-8597
Cardiology Administration	212-241-4030
Cardiology Appointments	212-427-1540
Cardiology Privileges	212-241-4029
Cardiothoracic Surgery	212-659-6800
Cardiovascular MRI and CT Imaging	855-MSHEART
Catheterization Laboratories	212-241-5881
Cath Lab Assistance ("any issues")	**212-241-0935**
Catheterization Laboratory Events	212-241-0592
Catheterization Laboratory Office	212-241-4021
Catheterization Laboratory Research	212-241-0229
Catheterization Laboratory Scheduling	212-241-5136
Coronary Care Unit	212-241-7222
Electrophysiology/Pacemakers	212-241-7272
Genetic Disorders	212-241-3303
Heart Failure/Transplantation	212-241-7300
Lipid Management	212-241-7651
Mount Sinai Heart Information Technology	212-241-4026
Noninvasive Cardiology	855-MSHEART
Pediatric Cardiology	212-241-8662
Pulmonary Hypertension	212-241-7300
To Transfer a Patient	**212-241-6467**
Vascular Laboratory	212-241-6773
Vascular Surgery	212-241-5315

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The mission of the Cardiac Catheterization Lab at Mount Sinai Heart is:

To improve outcomes and safety of our interventional patients by using a team concept to deliver clinical innovations, unrivaled research, and personalized clinical care.

Mount Sinai *Heart*