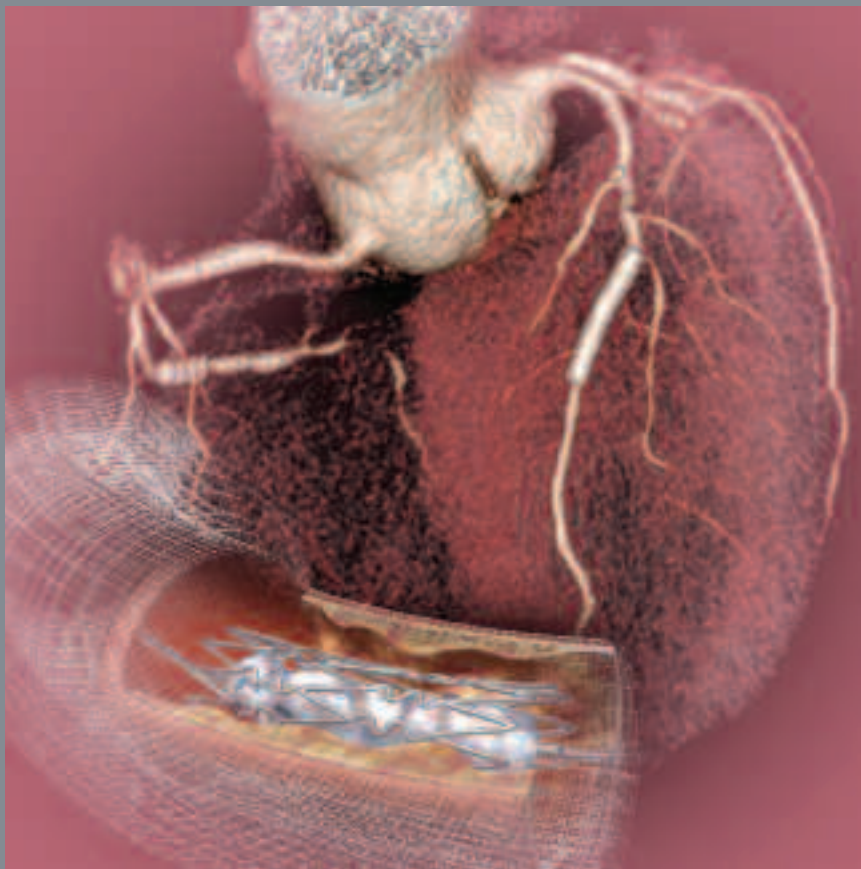


CARDIAC CATH LAB

2009 CLINICAL OUTCOMES REPORT



A MESSAGE FROM DR. SHARMA



Samir K. Sharma, MD
Professor Medicine, Cardiology
Director, Cardiac Cath Lab
& Intervention

Dear Colleague:

The staff of the Cardiac Catheterization Laboratory at Mount Sinai Heart takes great pleasure in presenting this clinical outcomes report. In this inaugural issue, we offer a comprehensive overview of the work being done at the nation's largest and finest cardiac catheterization laboratory in diagnosing and treating a variety of cardiac disease states.

On the following pages, details of the cardiac procedures performed in our Cath Lab over the last five years demonstrate the remarkable growth our group has achieved at a time when many cardiac centers in the country are facing declines in volume. This growth is accompanied by declining complications, made possible by a dedication to teamwork and to caring for each patient as an individual. We are also committed to the universal use of evidence-based standardized medical protocols and this has contributed to our extraordinary success. For these reasons, it is not unusual for patients in the region, many who have been deemed "inoperable for advanced care," to seek treatment here.

We understand that matching a patient with the right procedure as well as thorough post-operative management are just as or even more important than successfully performing the procedure itself. We believe in doing things right the first time and that every procedure, from routine to rare, deserves the highest level of professional expertise.

In this report we also provide details of innovations we have developed that have contributed to our national recognition. These innovations, combined with cutting edge research, ensure that our program remains a leader. Patients who can benefit from ongoing trials at our center are routinely offered the opportunity to participate.

Lastly, the most powerful advertisement of our program are the patients themselves and their success stories, some of which we will share with you in these pages. We are poised to realize the dream of Andreas Gruentzig, father of angioplasty – *to perform catheter-based percutaneous interventions with extreme safety for all vascular disease states in alert, awake patients.*

TABLE OF CONTENTS

Overview

What We Do	3
Results	7
Innovations	14
Research and Clinical Trials	29
Patient Success Stories	33
Key Staff Biographies	39
Voluntary/Part-Time Faculty	43
Annual Symposium	49
Mount Sinai Heart Directory	50

Mount Sinai Hospital Cardiac
Cath Lab: Clinical Outcomes
2009



WHAT WE DO

Mount Sinai Heart: The Cardiac Catheterization Laboratory

Mount Sinai Heart is a key division of Mount Sinai Medical Center. Under the leadership of visionary director Valentin Fuster, MD, PhD, Mount Sinai Heart has emerged as a premier center delivering an extraordinary range of clinical and research activities to patients suffering from a variety of cardiovascular ailments. Many clinicians, scientists, nurses and associated caregivers are engaged every day in our clinical facilities and invasive & non-invasive laboratories providing leading-edge diagnosis and treatment and bringing our patients and their families the very best that modern cardiovascular science can offer.

Left to right: Dr. Michael Kim,
Dr. Prakash Krishnan,
Dr. Samin Sharma, Dr. Pedro
Moreno, Dr. Annapoorna Kini

The Cardiac Catheterization Laboratory at Mount Sinai Heart is one of the most prolific interventional catheterization laboratories in the United States. Our Cardiac Cath Lab, made

up of five adult cath rooms, one pediatric room, one biopsy room and two electrophysiology rooms, has established itself as a tertiary center for complex coronary, valvular and vascular interventions. The attributes that set us apart from other centers in the region and across the U.S. are both the reason for and evidence of our success and unmatched reputation. Following are some of the important aspects of the Cardiac Cath Lab:





- **Volume:** Though many cardiac centers have seen declines in interventional volume over the last few years, the volume of interventions at Mount Sinai Heart Cath Lab continues to rise each year as illustrated in the chart on page 7. In 2008, we experienced remarkable increase in volume for nearly every procedure and in both coronary and vascular interventions with a new record of 5,274 adult cardiac interventions (highest in the country). This growth is due in part to our various outreach activities – allowing community physicians, the integral part of the Mount Sinai referral network, to offer tertiary care to their patients in the local catchment area. Due to our established reputation for handling complex coronary and valvular cases with great success and safety, about one third of our interventional patients are referred by physicians (cardiologists & interventionalists) outside our network.

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Mount Sinai Heart Cath Lab's consistently great procedural outcomes are a direct result of the establishment of standard protocols, rigorous attention to small details, the high volume of operations and the strong sense of teamwork among all staff members and ancillary support services.

as emergency cases. For the years 2003-2005, the New York State DOH has started reporting 30-day risk adjusted mortality and our incidence of 0.7-0.9% for all PCI cases and 2.4-2.5% for emergency PCI cases are among the lowest for any high volume cath labs and about 30% lower than the statewide average. Mount Sinai Heart Cath Lab's consistently great procedural outcomes are a direct result of the establishment of standard protocols, rigorous attention to small details, the high volume of operations and the strong sense of teamwork among all staff members and ancillary support services.

- **Interventional Results:**

Despite high complexity and co-morbid conditions of patients treated in our Cath Lab, procedural outcomes and complication rates of coronary interventions are among the best in the country. Reports of PCI mortality over the last 10 years by the NYS Department of Health have consistently placed the Mount Sinai Heart Cath Lab amongst the lowest for in-hospital mortality for all cases as well

- **Clinical and Basic Research:** In addition to clinical success, the Cath Lab has participated in numerous single-center and multi-center trials in the field of coronary interventions. The results of many of these endeavors have resulted in approval of new drugs and devices by the FDA to improve the outcome and safety of percutaneous interventional procedures. Also, key scientific publications on various PCI outcomes from our huge interventional database (approximately 20,000 cases) continue to advance the field of interventional cardiology in a safe and progressive manner.

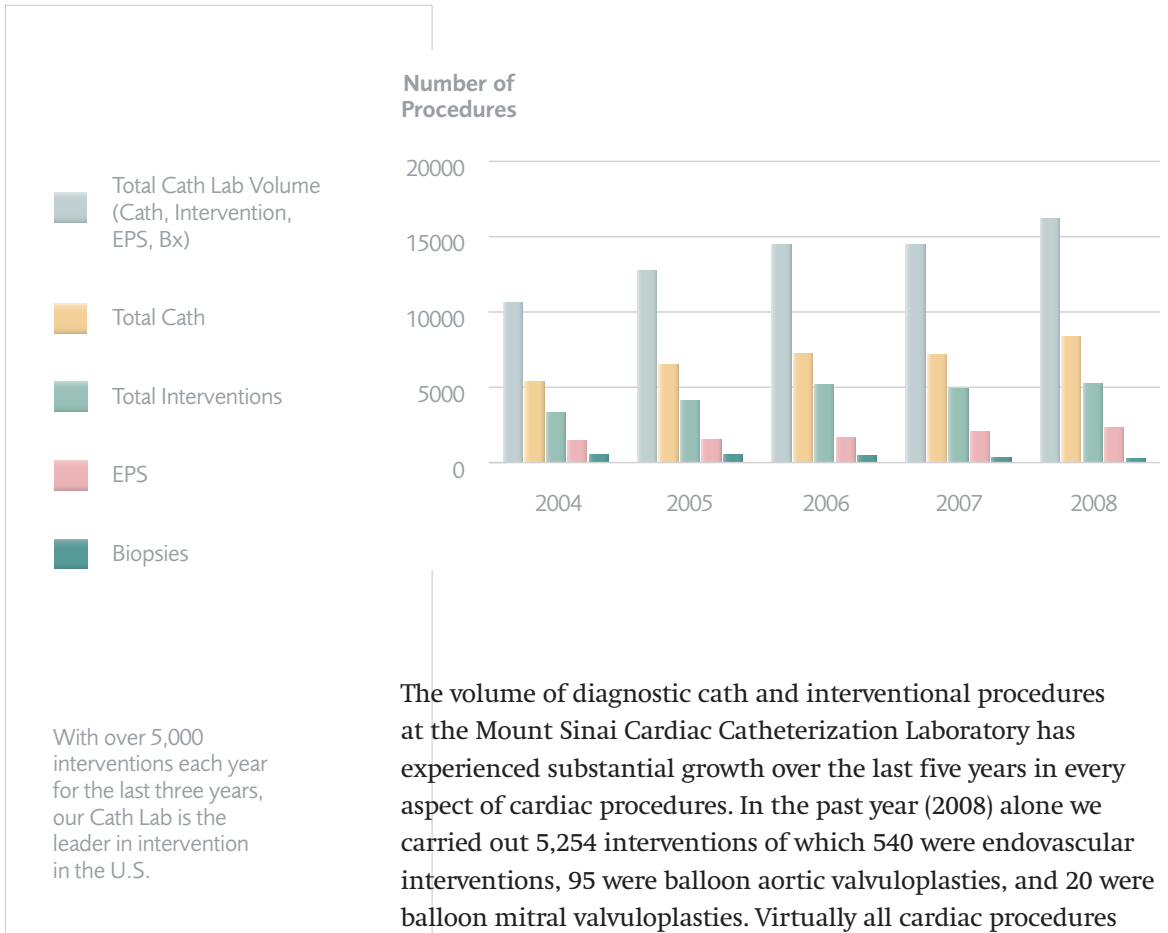
- **Cath Lab Staff:** The numbers of both medical and non-medical staff have grown tremendously to cope with the increasing volume while still delivering safe, superb care. Presently there are five full-time and 12 voluntary/part-time interventionalists, two CHF/Transplant attending, three EP attendings, seven interventional fellows, three EP fellows, and 10 nurse practitioners. The total number of Cath Lab staff including nurses, technician and support staff is over 130, along with a nurse manager, operational manager and nursing director. Each member of the Cath Lab staff has a strong work ethic and takes pride in their contribution to the goal of the department – delivery of efficient and safe care to patients in need. As a result the Cath Lab reports a very high level of patient satisfaction.

While the Cardiac Cath Lab at Mount Sinai Heart handles a remarkable volume of patients, we are most proud of our record of high patient safety and low mortality.



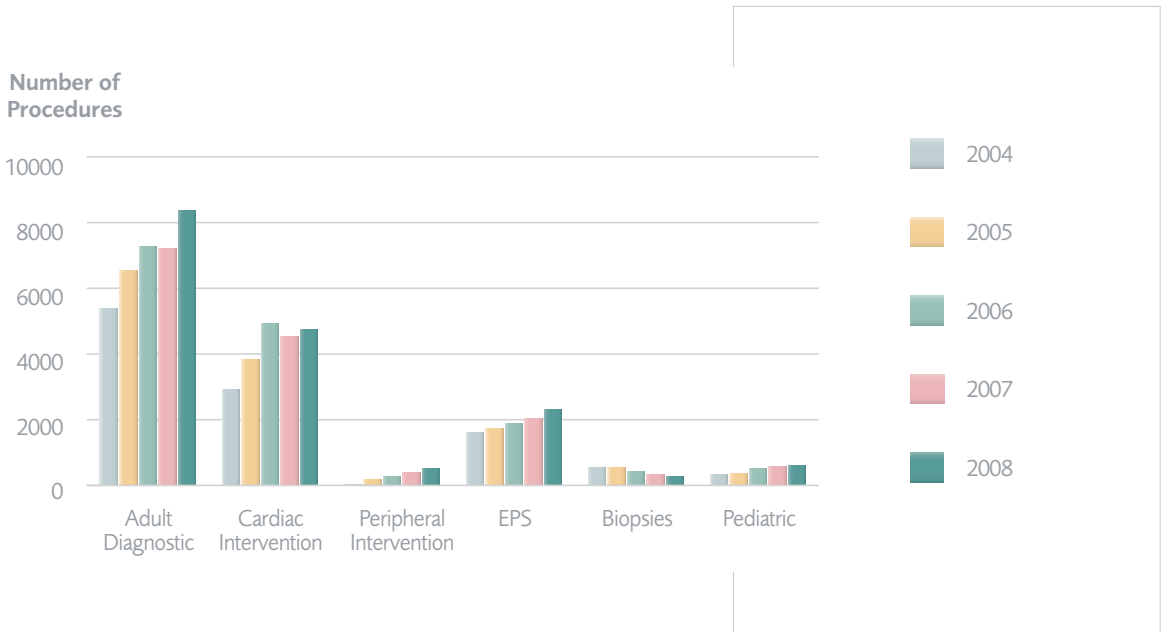
RESULTS

Growth in Cardiac Cath Lab Volume



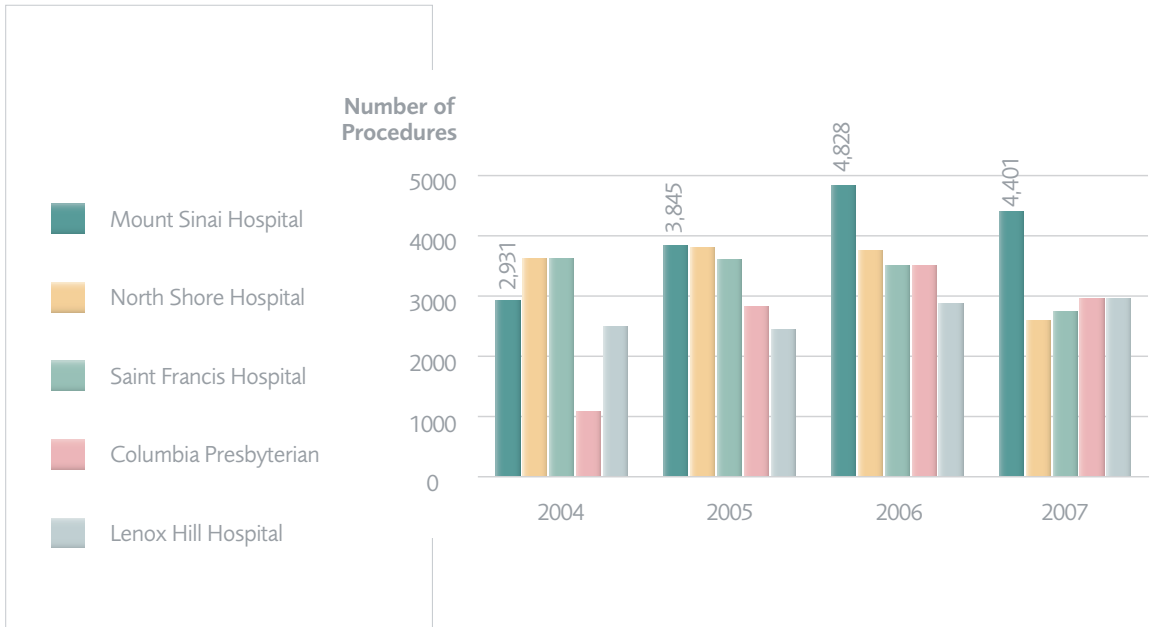
The volume of diagnostic cath and interventional procedures at the Mount Sinai Cardiac Catheterization Laboratory has experienced substantial growth over the last five years in every aspect of cardiac procedures. In the past year (2008) alone we carried out 5,254 interventions of which 540 were endovascular interventions, 95 were balloon aortic valvuloplasties, and 20 were balloon mitral valvuloplasties. Virtually all cardiac procedures have increased in volume in recent years, the exception being biopsies, which have declined along with transplant volume, as patients are treated through other means.

Trends in Volumes of Procedures



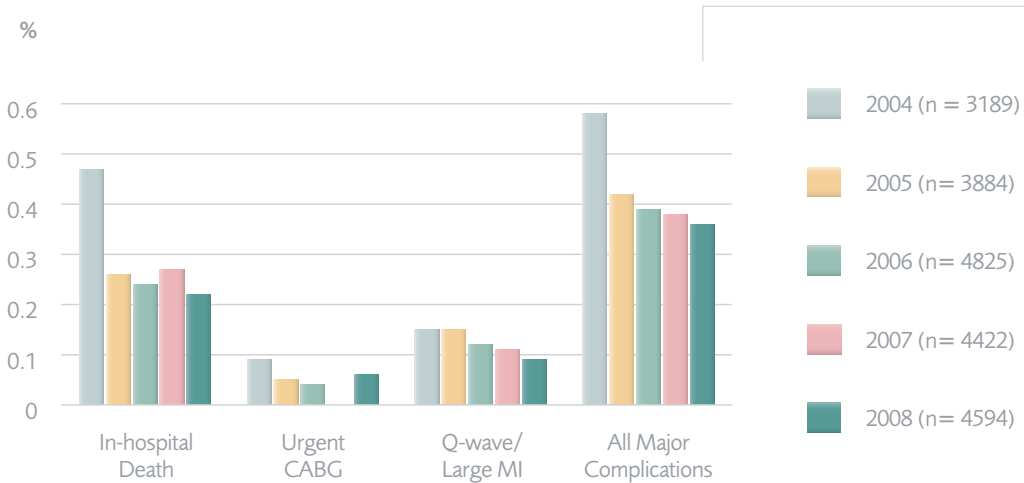
Coronary interventions (also known as percutaneous coronary interventions, or PCIs, which use stents and balloons) encompass a variety of procedures used to treat patients with diseased arteries of the heart. Peripheral (or endovascular) interventions are those that address disease in limbs and renal arteries. Pediatric cases, shown in the grouping on the far right of the chart, include repair of atrial septal defects (ASD) and patent foramen ovale (PFO) closure. This last category, performed by our pediatric cardiologist Dr. Barry Love, is not counted in our interventional numbers.

NYS-DOH reported PCI volumes



Mount Sinai Hospital's Cardiac Catheterization Laboratory is one of the busiest in the country and the most active center statewide. Growth has been tremendous over the past five years, as the above chart shows. Our lab has risen from third position among New York State hospitals in 2004 to assume a commanding lead in 2007, with growth occurring in both coronary and non-coronary (or endovascular) interventions. Data is taken from the state's own Department of Health statistics.

Temporal Complication Trends



Major complications of Percutaneous Coronary Interventions include death, a heart attack (MI), or an urgent need for open heart surgery (CABG) as a result of the procedure. The sum of those numbers for the past five years represents less than 0.5% and in-hospital mortality less than 0.25%. These low complication rates, credited to a uniform protocol across all staff, are all the more remarkable for the fact that our Cath Lab accepts the most difficult coronary cases, many of them deemed too risky or “not-doable” elsewhere. The comparative data of patients’ clinical characteristics, as shown in the table on page 11, confirms significantly higher adverse features of PCI patients treated at MSH compared to New York State. Also, a comparative complication rate of PCI at MSH cath lab with New York State and ACC-NCDR is shown in the attached graphs and summarizes our complications rates as one third to half of the reported standards.

With an average mortality rate of <.25%, the chance of in-hospital patient death is less than 1 in 500.

Baseline Demographics and Risk Factors of PCI

Comparison of Mount Sinai Hospital 2008 vs.
New York State 2005

	MSH (N = 4,615)	NYS (N = 56,245)
Age >80 yrs (%)	12.5*	10.1
LVEF <30% (%)	4.9	4.5
S Cr >1.5 mg/dl (%)	13.3*	10.1
Previous MI (%)	29.0*	21.2
Peripheral vascular disease (%)	14.9*	7.1
CHF (%)	13.1*	8.6
COPD (%)	8.9	6.1
DM on medication (%)	44.6*	31.5
Renal failure, dialysis (%)	3.1*	1.9
Stent thrombosis (%)	0.4	0.3
Previous organ transplant (%)	1.3*	0.3
2/3 vessel CAD (%)	31/20	30/13
Rotational atherectomy (%)	5.8*	1.7
DES use (%)	72.2	64.2

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

* P <0.05% For Mount Sinai Hospital vs. New York State.

Major Complications Following PCI

Comparison of Mount Sinai Hospital 2008 vs. New York State 2005

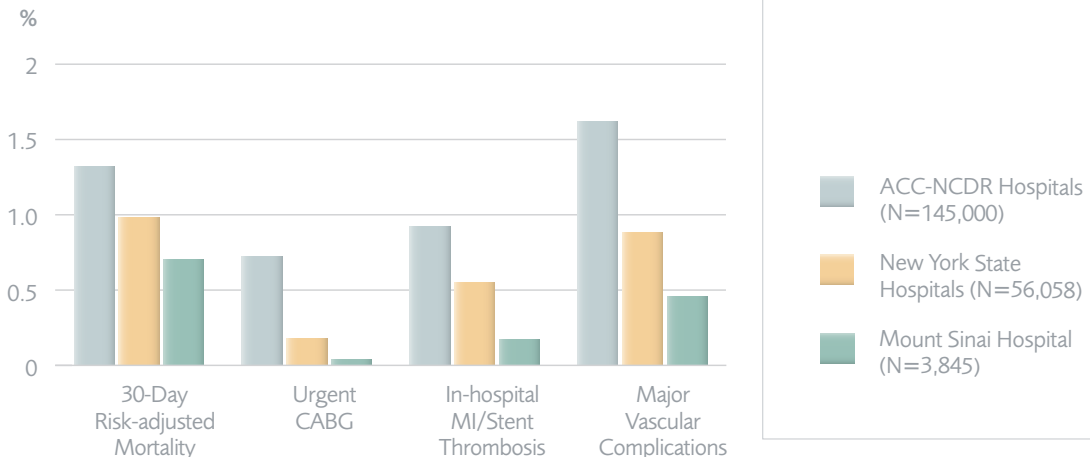
MSH (N = 4,613) NYS (N = 56,245)

In-hospital mortality (%)	0.24*	0.54
Trans-mural MI (%)	0.03*	0.11
Emergency cardiac surgery (%)	0.06*	0.18
Acute occlusion target vessel/SBr (%)	0.15*	0.32
Stent thrombosis (%)	0.18*	0.44
Emergency return to cath lab for PCI (%)	0.03*	0.12
Stroke (%)	0.06*	0.08
A/V injury at cath entry site (%)	0.27*	0.33
Renal failure requiring dialysis (%)	0.09*	0.11

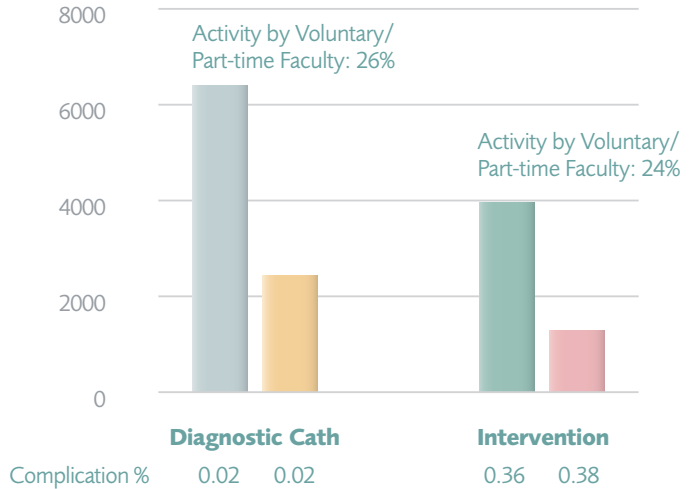
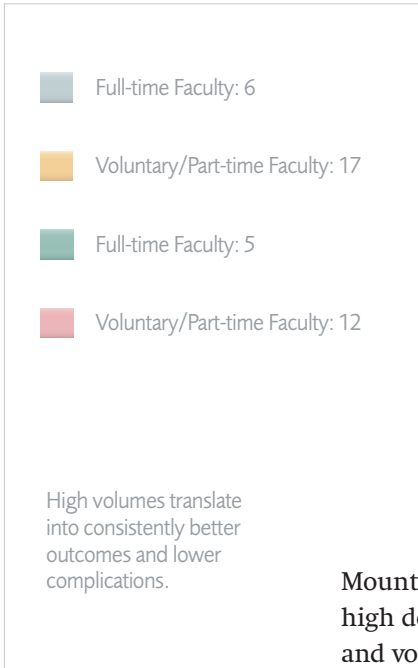
* Complications are substantially lower than state average.

Across all categories, major complications are a third to half of published state and national benchmarks.

30-Day Risk Adjusted Mortality and Complications of PCI 2005



Cath Volume by Full-time vs. Voluntary/Part-time Faculty 2008



Mount Sinai Heart Cath Lab has been able to successfully meet the high demand for services by utilizing a combination of full-time and voluntary/part-time invasive cardiologists and interventionalists. All these specialists work under the same protocols to ensure consistency and quality of care, which is especially important when considering the large caseload of acute patients – many of them added on an emergent basis. Sampled for 2008, voluntary/part-time faculty accounts for approximately 25% of diagnostic cath and interventional volume. Overall, procedural complications have been similar amongst full-time versus voluntary/part-time attendings (0.36% vs. 0.38% respectively). This again is the result of teamwork, standardized protocols and assistance by the expert senior interventionalists in tough, complex cases, or during any unexpected procedural complications.

INNOVATIONS

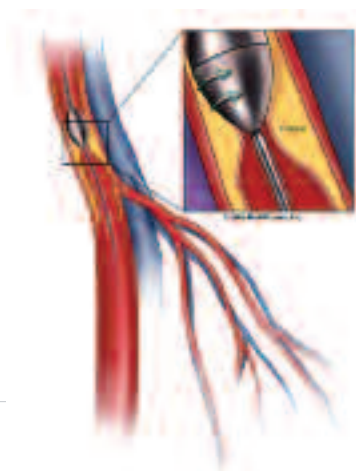


Samin K. Sharma, MD Director, Cardiac Cath Lab & Intervention on Complex Coronary Interventions

Many cardiac centers are facing static or declining interventional volumes, due in large part to the wide use of drug-eluting stents, which have reduced the incidence of restenosis. By contrast, the Mount Sinai Cath Lab continues to see annual increases in patient volume in all categories of intervention. Our reputation for efficiency, quality of care, and our unmatched low rate of complications, certainly contribute to this growth. Perhaps an even more decisive factor is our willingness to step out of the box to take on and perfect the complex cases from which other centers tend to shy away.

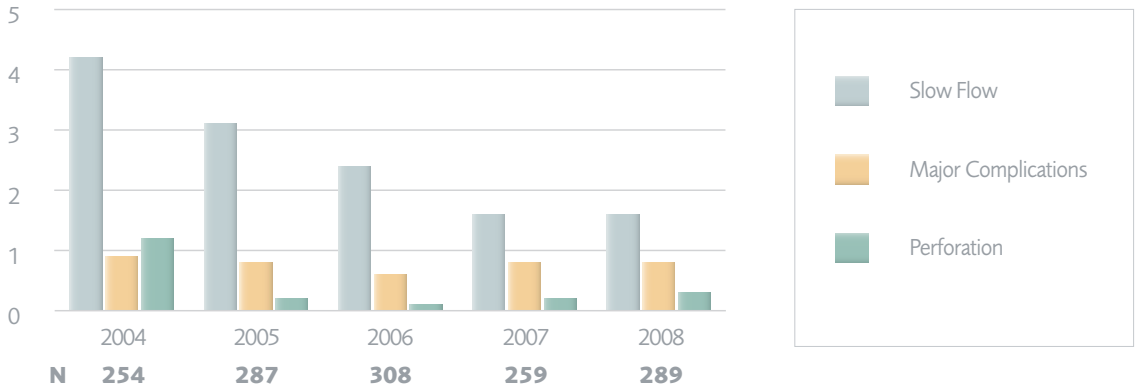
Complex coronary interventions can be defined as those in which the risks are high, either because of the patient's age and general health, or because access to the blockage is difficult. Our ability to handle these complex cases and the volume with which we see them makes us effectively a tertiary center for PCI. I want to cite three complex cardiac procedures that are of particular note at Mount Sinai: rotational atherectomy, interventions of unprotected left main (ULM) coronary artery, and balloon aortic valvuloplasty (BAV) for elderly non-operable patients.

Rotational atherectomy is a specialty for which we are particularly known and allows us to safely treat tough calcified blockages. We are coincidentally the highest user of this technique in the country. The device, the Rotablator[®], was introduced by Boston Scientific in its earliest version in 1992. It consists of a very high-speed drill with a selection of abrasive microdiamond-coated burrs at the tip. Using foot pedal controls, the burr revolves at 130,000 - 170,000 rpm. In the hands of an



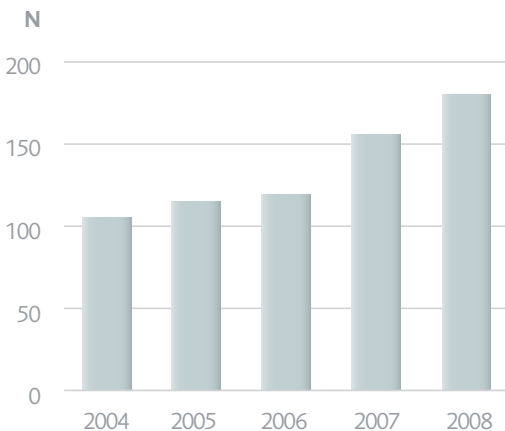
Mount Sinai Heart Cath Lab is
the highest user of rotational
atherectomy in the U.S.

Rotational Atherectomy: MSH Experience and Complications



experienced interventionalist it gently pulverizes the calcified blockage in one to three minutes, turning the obstruction into a powder that safely flushes out of the body. The patient, who is only locally anesthetized, experiences the procedure as something akin to having a tooth drilled. After the blockage is removed we open the vessel further by inflating either a regular balloon or a knife-bladed (cutting) balloon. Finally, a stent is usually deployed, compressing any residual plaque between it and the inner vessel wall. Within a very short time the patient has improved blood flow and heart function.

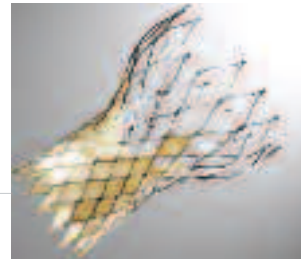
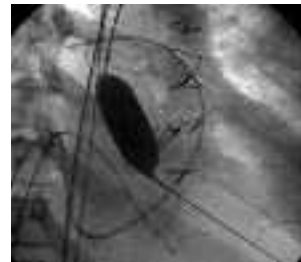
Volume of Unprotected Left Main (LM) Coronary Artery PCI at MSH



PCI of unprotected left main (ULM) coronary artery is typically performed in high-risk surgical cases. Many of them require rotational atherectomy as a result of advanced age and heavy calcification. We have been identified as the center of excellence for left main coronary artery intervention, with an overall success rate of >99% with major complications of <1% in all cases. Our team of interventionalists and cardiac surgeons evaluate each patient with a ULM lesion to deliver the most appropriate treatment.

Balloon aortic valvuloplasty (BAV) is a non-surgical palliative approach to treating severely symptomatic aortic stenosis when surgical replacement of the aortic valve via heart bypass is not appropriate. The idea of percutaneous treatment of aortic stenosis by balloon catheterization was first put into clinical practice in the 1980s, but various complications eventually led to its falling out of favor at many interventional centers. Mount Sinai, however, has had continued success with the approach, performing an average of 90-95 procedures each year with a major complication rate of <6% that is notably lower than the state average (8%). The cohort of patients we treat are typically elderly (average age 85, but some over 100) and they often have multiple co-morbid conditions, which may include a past stroke, and/or some lung disease or diabetes. Other interventional cardiologists who don't have sufficient experience in this technique refer many of these patients to us.

The basic procedure for BAV is to insert a single balloon or series of progressively larger balloons to open up the stenotic aortic valve percutaneously. But as compared with surgical treatment, which is not an option in the elderly high-risk patient, simple BAV is at best a form of palliative intervention. We have published our outcomes and have shown that BAV is often repeated after 9-12 months and repeat BAV up to three times may extend life for 3-4 years in these high-risk, no-option patients. The larger goal for these patients is to non-surgically replace the entire stenotic aortic valve (percutaneous valve replacement). This procedure is already being offered clinically in Europe and Canada, and later this year we will be participating in a randomized trial to establish the safety of this approach using Medtronic's new CoreValve ReValving® system. The CoreValve is an aortic prosthesis composed of three bovine pericardial leaflets sutured within a self-expanding nitinol stent. It is inserted as a single unit via a specialized catheter and popped into place at the site of the native valve, crushing the old valve against the vessel walls in the process.



Top: Balloon
Aortic Valvoplasty
Bottom: CoreValve



Annapoorna S. Kini, MD Associate Director, Cardiac Cath Lab & Intervention on Alcohol Septal Ablation

In the past there were ways to treat hypertrophic obstructive cardiomyopathy (HOCM): through medical management with beta-blockers, calcium channel blockers, and other drugs that slow the heart rate and increase the heart's ability to fill; through implantation of a pacemaker to change the pattern of contraction to one that is more efficient (no longer a preferred route due to questionable long-term effects of this treatment modality), and through open heart surgery and the surgical removal (myectomy) of overgrown heart muscle to enhance blood flow from the left ventricle.



Normal heart
(cut section)



Hypertrophic
cardiomyopathy

Mount Sinai's Cath Lab is one of relatively few high-volume centers offering a small group of patients with symptomatic obstructive HOCM a fourth choice. Known as alcohol septal ablation (ASA), this minimally invasive procedure does not require general anesthesia or lengthy recovery time, and is only rarely associated with the complications sometimes found in open heart septal myectomy. ASA is now the second treatment option for the selected group of HOCM patients, who are on maximal medical therapy.

ASA is done percutaneously, avoiding surgery but with similar success in terms of removing overgrown heart muscle. The procedure involves the slow, selective injection of 100% alcohol via catheter into one of the branches of the heart artery that goes to the enlarged septum. The high concentration of alcohol from 1 to 3ccs is delivered directly to the thickened heart muscle and left in place for several minutes. The effect starts immediately with controlled cell death at the target location. Typically, the goal is to remove no more than two grams of obstructive muscle mass; more could cause irregular

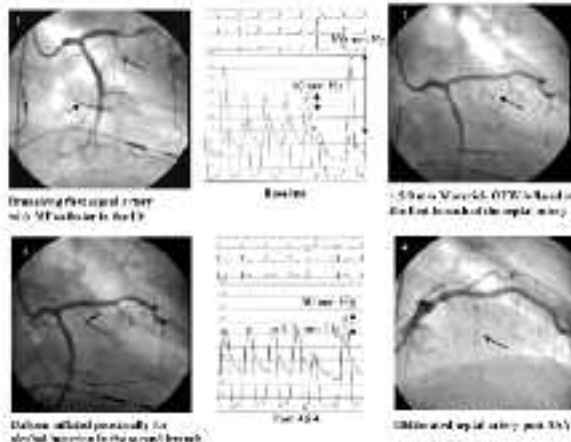
Mount Sinai's Cath Lab is one of relatively few high-volume centers offering a small group of patients with symptomatic obstructive HOCM a choice of alcohol septal ablation.

heartbeat and require a permanent pacemaker. However, as we are able to watch the heart from all sides via X-ray fluoroscopy and echocardiography, we can assure correct catheter placement and destroy only what is necessary. Thanks to our extreme care in selecting patients and the protocols we have in place, our complication rate for ASA has been zero in the last three years.

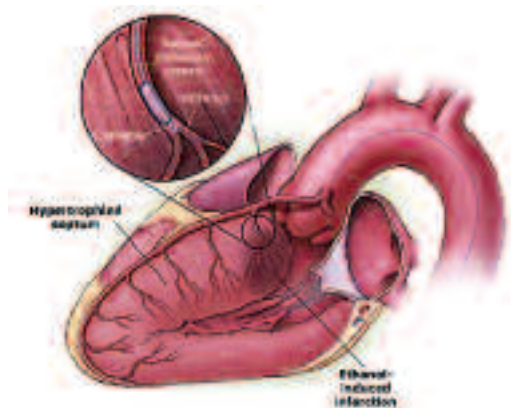
ASA patients are then closely monitored in the ICU for two days. We are particularly attentive to arrhythmias and to blood chemistry, tracking the volume of creatine kinase (enzyme) leakage to tell us the extent of the controlled damage. From 700 to 1,500 enzyme units per liter is what we look for. Patients typically report feeling better almost immediately and once safely stabilized, they are able to go home on restricted activity for 2 to 4 weeks. The ablative process is completed in several weeks as a thin layer of scar tissue forms and LV diastolic function improves. We do follow-up echocardiograms of the post-operative patient in 3 to 6 months.

In selecting patients for this procedure the standard is a hypertrophic heart muscle that is between 16 and 28mm thick. Less than that is borderline HOCM and usually responsive to medical management; more than 28mm is too dangerous to undertake by ASA. The condition of obstructive cardiomyopathy is usually of genetic/familial origin and reveals itself in the patient's 20s or 30s. Another subgroup (a rare entity) is mid cavity obstruction in HOCM affecting elderly women with hypertension. We have performed ASA in this group of patients with good symptom relief.

Alcohol Septal Ablation (ASA) for Hypertrophic Obstructive Cardiomyopathy



The benefit of alcohol septal ablation is noticeable immediately after the procedure and symptoms continue to improve over time.



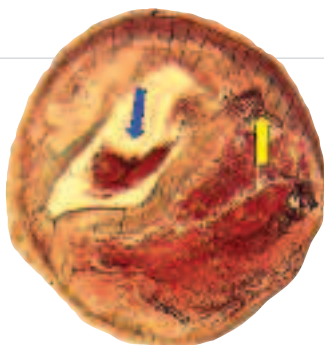


Pedro R. Moreno, MD Director, Interventional Research, Cardiac Cath Lab on Vulnerable Plaque Imaging

Our understanding of the nature of atherosclerosis has changed considerably.

Until recently, cardiologists thought that the cause of most heart attacks was the narrowing of a coronary artery and the buildup of plaque that progressively would slow blood flow, and eventually result in total blockage. These kinds of occlusions could often be detected and treated prophylactically based on warning symptoms of angina and chest pain, a stress test, and a diagnostic angiogram. But heart attacks also develop in people with relatively mild atherosclerosis, and research is now focused on learning more about the vessel wall and the composition of the plaques that accumulate there. A crucial factor in terms of relative risk is plaque composition – whether it is relatively stable and likely to remain embedded in an arterial wall or is “vulnerable” and prone to rupture, break free to become a clot that clogs an artery and causes thrombosis, as shown at left. The differential diagnosis of vulnerable plaque (VP) is only now becoming possible through advances in coronary imaging technology.

Plaque rupture and thrombosis:
Histological example
of coronary atheroma
complicated by plaque
rupture (yellow arrow) and
thrombosis (blue arrow).
Courtesy of Dr. Purushothaman,
Mount Sinai Hospital, 2009.



The Interventional Research arm of the Cardiac Cath Lab at Mount Sinai is one of the sites engaged in developing this technology. On the basis of histological studies, we know that the type of plaque most vulnerable to disruption is a thin-capped, soft, lipid-rich fibroatheroma. VPs are further characterized by the presence of inflammatory cell content (macrophages), positive remodeling (compensatory enlargement of the vessel), and increased neovascularization. Our studies to date indicate that VPs occur most often in patients with acute coronary events; using triple artery intravascular virtual histology we can detect VP in 38% of the patients.

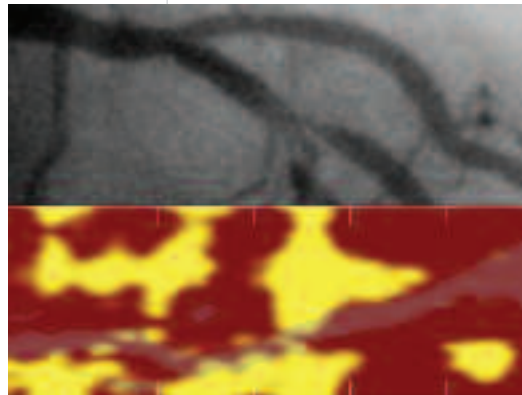
Multiple techniques to identify these potentially lethal plaque types early in their progression have been tested, including thermography, intravascular ultrasound, and angiography, all with limitations. Our approach combines diffuse reflectance near-infrared spectroscopy with software algorithms we have developed to analyze the differential absorption of light of the chemical contents of VPs. I hold the patent for the application of infrared spectroscopy for the identification of VP in humans and am co-founder of InfraReDx. This LipiScan™ system consists primarily of a laser light source and a small fiberoptic catheter, as shown at right. This catheter received FDA approval in 2008.

In addition to diagnosis, the lab is also testing novel therapies as potential adjunctive treatments for vulnerable plaques.

Other areas of investigation in my research lab include defining the basic cellular, molecular and genetic pathways of atherosclerosis neovascularization in the diabetic population and distinguishing the markedly different susceptibilities to oxidative stress generated by intra-plaque hemorrhage. This susceptibility appears to be under genetic and epi-genetic control. The extravasation of hemoglobin after hemorrhage triggers pro-inflammatory response that is antagonized by the Haptoglobin protein. Current ongoing studies evaluate the tissue characteristics and the mechanistic pathways of atherosclerosis characterized by the Haptoglobin genotype in patients with peripheral vascular disease. This is of significant relevance in the diabetic population in which the Haptoglobin genotype plays a major role in major adverse cardiovascular events. Proper genotyping in this population will allow for individualized therapy (pharmacogenomics), with a potentially huge impact on the incidence of cardiovascular events.

Upper panel: Coronary angiography showing a bifurcation lesion in the left anterior descending coronary artery.

Lower panel: LipiScan™ imaging of the same lesion showing a large lipid core (yellow). Courtesy of Dr. James E. Muller, InfraReDx





Michael C. Kim, MD Director, Coronary Care Unit on Ambulatory PCI

For the past nine years we have been the national leader in Ambulatory PCI, which is the practice of safely sending home patients within six hours of percutaneous coronary interventions. It's an approach that is being followed with regularity in Europe and Canada, but is still rare in the U.S. Based on a number of criteria which we have developed about 20% of Mount Sinai patients meet the eligibility guidelines.

The Mount Sinai Heart Cath Lab can offer ambulatory PCI to so many patients because we have pioneered a uniformly observed protocol that allows us to do this safely and consistently.

From the point of view of the patient, the medical center, and the cost variables involved, being able to offer ambulatory PCI is a tremendous advantage. For the patient, who would almost always rather sleep in his own bed, being able to go home safely the same day is experientially a huge change. Only a decade ago, the stay might have been as long as a week due to anticoagulation issues and vascular complications. And in most catheterization complexes around the country today an overnight stay is still the standard of care, despite all the technological advances that have come along in terms of drug-eluting stents, cutting balloons, reduced doses of anticoagulants, and imaging devices.

We can offer ambulatory PCI to so many because Mount Sinai interventionalists have pioneered a uniformly observed protocol that allows us to do this safely and consistently. In turn, ambulatory PCI increases thru-put in our lab while freeing up beds for more complicated cases. We think these achievements will inevitably become the model for other high volume centers as they seek to handle patients more effectively, with greater cost efficiencies, in the future.

The 20% who are currently being afforded same-day discharge from Mount Sinai's Cath Lab are those who have fairly straightforward procedures with no complications.

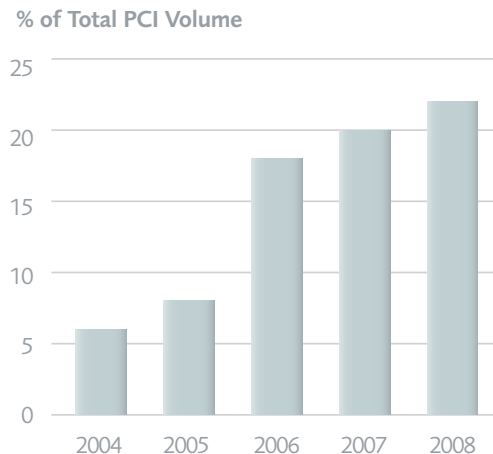
Though most are under 65, by careful screening we have occasionally been able to provide ambulatory PCI to patients as old as 85. A key element in same day discharge is advances in vascular closure devices (VCDs). Complications related to vascular access, particularly at the femoral artery site after coronary angiography and PCI interventions, were among the more common adverse events that used to occur when manual compression or the original VCDs were used to seal an opening following catheter withdrawal. The newest generation of VCDs, however, has proved to have significantly lower risk, especially in the hands of interventionalists who do a high volume of cases.

At Mount Sinai we use several different VCDs including the suture-mediated Perclose®, the combination collagen and suture Angio-Seal®, and the clip-mediated StarClose®.

We then monitor patients closely in the observation area for 4-6 hours, using EKGs and blood work-ups to check for any adverse developments. Patients who continue to do well are then ambulated by support staff and assessed by a PCI-trained nurse who reviews their prescription supply, goes over necessary home care instructions and symptoms, and answers any questions the patient and family may have. When all signs are go, the doctor gives the final discharge.

The Cath Lab is currently participating in the ABCD (Ambulatory Closure Device)-PCI trial, a multi-center randomized study of over 200 patients to evaluate patient satisfaction, safety, and cost-effectiveness. We believe that the favorable results we document will alleviate any remaining patient or referring doctor concerns.

Volume of Ambulatory PCI at MSH





Prakash Krishnan, MD Director, Endovascular Intervention, Cath Lab on Advances in Treating Peripheral Artery Disease

Peripheral artery disease has emerged as an important factor influencing long-term outcomes of cardiac patients.

Top: iliac angiogram before procedure

Bottom: iliac angiogram after procedure



Endovascular intervention is catheter-based therapy used to treat peripheral artery disease (PAD). PAD is a form of atherosclerosis in which plaque builds up in one or more peripheral arteries carrying blood to the head, organs and limbs, eventually leading to significant obstructed flow. PAD occlusions are most commonly found in the legs, but may also occur in the carotid, vertebral, renal, iliac, femoral, popliteal and tibial vessels. Smoking is the major risk factor, followed by diabetes, elevated serum cholesterol, high blood pressure, and prolonged sedentary life. PAD can cause a variety of symptoms depending on where the occlusion occurs. Blocked blood flow in the legs can cause pain and numbness, slow healing of wounds, and ulcerations; in severe cases it can lead to gangrene and even amputation. Occlusions in the carotids may trigger a transient ischemic attack or stroke. Renal artery blockages may provoke hypertension. Subclavian occlusions can lead to angina, and iliac occlusions to buttock claudication, which can be present as hip arthritis.

Peripheral artery disease is diagnosed through objective testing. The most sensitive preoperative test we use is the ankle brachial index (ABI), which compares pressures in the lower leg and arm. As pressure at the ankle and calf are normally equal to that in the arm, differences can be used to localize the obstruction with 99% specificity.

Endovascular cath and intervention itself is very simple, similar to coronary angiography. We usually enter contra laterally through the femoral artery of the leg opposite the leg of interest because this positioning is much more comfortable for the patient and the physician. We follow the arterial tree and its branches until we get to the point where we can take

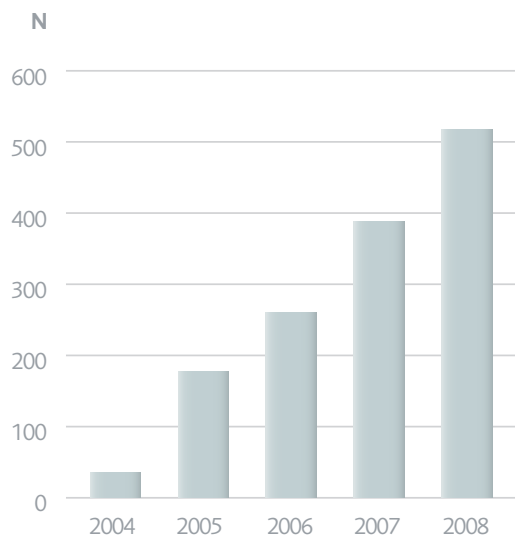
a real time angiographic picture. Once we see the blockage we make the clinical decision as to what to do.

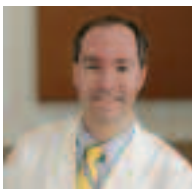
Multiple strategies have been developed to traverse and treat obstructions, depending on their locations and compositions, and this is where having a high volume of cases is especially valuable. We may use various stents, bare and drug-eluting, rotational, directional and ablative atherectomies, jet stream, orbital, and laser therapies, as well as cryolysis and thrombolysis.

Legs, for example, are constantly in motion, with the result that stents may be less appropriate here because they are less able to withstand the tension, flexion, torsion, and other stresses that the active leg undergoes.

Hospital caseloads of endovascular interventional cardiology treatments are not enumerated by the state as are some other procedures, so there are no exact numbers by which to make comparisons, but we're definitely among the top three centers regionally, and at Mount Sinai nobody does more than I do. We started the endovascular intervention program about four years ago and to date we've done about 2,000 (or close to 500 cases per year). Our complication rate is extremely low, with 0% major and less than 0.5% minor complications. The patient comes into the hospital in the morning, has the procedure, and depending on age, home support and any co-morbid conditions that might require initial observation, goes home the same day or the next morning.

Exponential Growth of Endovascular Intervention at MSH



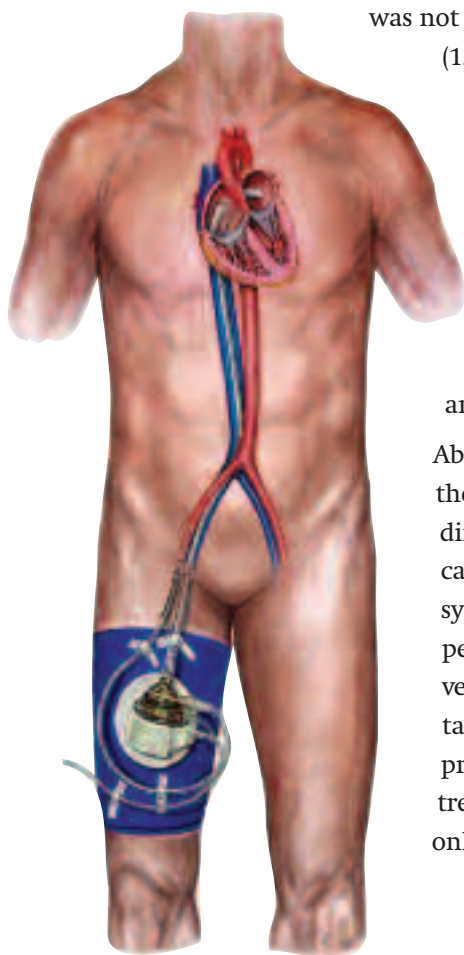


Sean P. Pinney, MD
Director, Advanced Heart
Failure and Cardiac Transplant
Program on Devices for
End Stage Cardiomyopathy

For many years the intraaortic balloon pump (IABP) was used extensively to provide temporary support to patients with acute heart failure, for whom invasive surgical ventricular assist was not an option. But the IABP's limited pump flow rates (1.5L/min) always made it less than fully satisfactory.

Now, however, we have a better alternative, which is a percutaneous ventricular assist system called the TandemHeart[®] from CardiacAssist. This device offers left atrial-to-femoral artery bypass through a system consisting of an in-flow cannula placed usually in the vena cava, an outflow cannula in the femoral artery, a centrifugal blood pump strapped to the leg, and a stand-alone controller to power the pump.

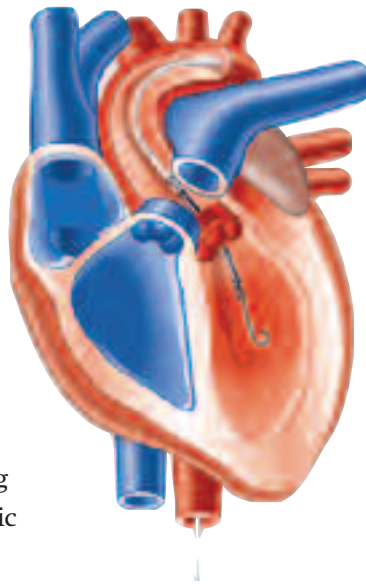
Able to provide flow rates greater than twice that of the IABP when needed, the TandemHeart provides direct reduction of the left heart's workload until cardiac stabilization and recovery occurs. The same system can also serve as a bridge until another permanent treatment such as an implantable ventricular assist device or a heart transplant can take over. At the Mount Sinai Cath Lab we can provide this critical assist 24/7, which gives us a tremendous advantage over cath labs that are open only during a more limited time. Its insertion also



requires a level of advanced technique that can usually only be found in centers which have high caseloads such as ours.

Still newer in the field of LV support is the Impella® LP 2.5 from Abiomed™. I think the Impella has the potential to change the treatment algorithm of cardiogenic shock, which occurs in approximately 7-10% of patients being treated for acute ST-elevation myocardial infarction (STEMI). Like the TandemHeart ventricular assist, the Impella reduces myocardial workload and oxygen consumption, but the Impella can be deployed percutaneously more easily and in less time, making it particularly appropriate in instances of cardiogenic shock where not only myocardial recovery is the objective but end organ perfusion and recovery as well.

The Impella LP 2.5 is essentially a catheter-mounted micro axial blood pump with external controller. The encapsulated pump motor (3mm) is inserted within a 4mm catheter via the femoral artery and positioned across the aortic valve into the left ventricle. Once in place, it pumps up to 2.5 L/min of blood from the left ventricle into the ascending aorta. It can remain in this position for up to five days as needed. The Impella LP 2.5 is currently undergoing clinical trials to expand its applicability to a wider range of patient conditions and Mount Sinai is a participant.



Mount Sinai Heart can provide percutaneous left ventricle assist devices 24 hours a day, seven days a week throughout the year.



Barry A. Love, MD
Director, Pediatric Cardiac Cath
Lab on Innovations in Treating
Atrial Septal Defect and
Patent Foramen Ovale

These days, patients with congenital heart defects come to our Cath Lab where we can offer them minimally invasive safe alternatives to heart repair.

Congenital heart defects may make themselves known in the infant or young child. Though many patients are not diagnosed until adulthood. The clues for the patient are likely to be increasing fatigue, shortness of breath and poor exercise tolerance for which no other causative factor is readily apparent. The symptoms often appear around the third decade of life. Indicators for their primary care physician may include abnormal heart sounds or murmurs on auscultation, cyanosis, and clubbing. Diagnostic imaging confirms the diagnosis. These days many of these patients come to our Cath Lab where we can offer them minimally invasive alternatives to open heart surgical repair.

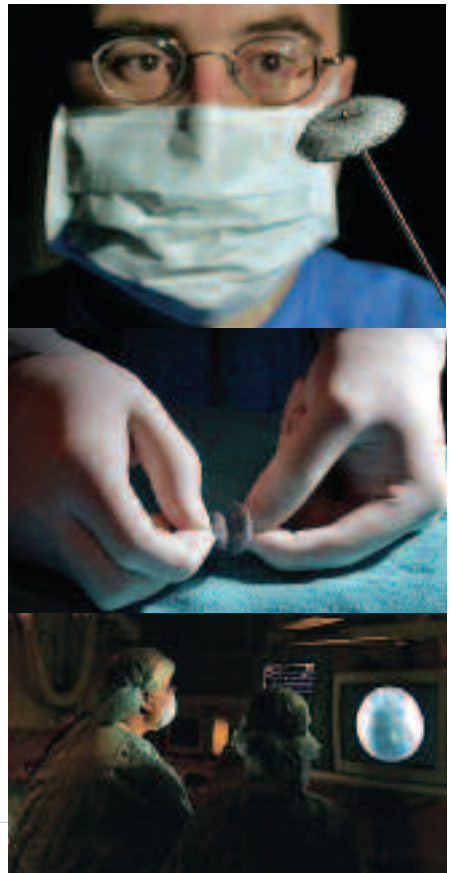
Atrial septal defects (ASDs) represent roughly 30% of the congenital heart defects seen in adults. The ASD is usually a single hole, but possibly more, in the wall separating the right and left atrial chambers. The amount of blood being improperly shunted left-to-right through the opening may remain relatively minor in childhood while the chambers are still fairly compliant. But as the patient reaches maturity and the left chamber naturally becomes less compliant, the shunting increases. The hemodynamic consequences of this leakage can lead to permanent damage, including atrial fibrillation, pulmonary hypertension, supraventricular arrhythmias, and eventually right-sided heart failure.

We have two ways to close an ASD. The one with a long and consistent track record is through surgical bypass. The other, relatively new way, is through ASD closure via catheterization using an implantable device that received FDA approval in the U.S. in 2002. The procedure is almost pain free, involves only local anesthesia and a short hospital stay, with a rate of complete closure greater than 97% and an incidence of major complications below 0.3%. We consider percutaneous repair the preferable option for patients with no other cardiac conditions requiring simultaneous surgical repair.

We begin the procedure with coronary angiography to assess the problem and to measure the size of the hole using balloon catheterization. We go on to do a percutaneous closure in the moving heart. Intracardiac echocardiography (ICE), a relatively new technology, plays an integral role in making this procedure feasible at each stage. The occluder we use is the Amplatzer,[®] a self-expanding device consisting of a polyester fabric interconnecting waist and circular double disc of biocompatible nitinol mesh that is unsheathed via catheter across the septal hole.

Another congenital condition that sometimes requires intervention in adulthood is Patent Foramen Ovale (PFO). The foramen ovale (FO) is a small normally occurring portal that exists in the fetal heart which typically closes at birth. But in some individuals closure is incomplete or patent to a lesser or greater degree, a situation known as PFO. As the patent foramen is pressure sensitive, it may never be symptomatic or only under certain conditions such as coughing, sneezing or forcing a bowel movement, a defect that is generally of no consequence. But in a small subset of patients the PFO can cause a TIA or cryptogenic stroke. The incidence may then be found to trace to a clot or particle in the blood, which has crossed directly from the right to left atrium, to go directly toward the head and lodgment in a cerebral artery.

The evidence is still out on the relative merits of medical therapy with blood thinners vs. PFO closure for some patients, but for those whose cardiologists recommend closure, the percutaneous approach is increasingly preferred over surgery. Our method of closing a PFO is similar to that of an ASD. We are currently one of the highest volume centers for ASDs and PFOs with more than 10 years of experience. And because of our familiarity with these congenital defects, we are involved in several multi-center studies, including one on the possible association between PFOs and certain refractory headaches.



Dr. Love showing the Amplatzer device and inserting in a 42-year-old patient with atrial septal defect.

RESEARCH AND CLINICAL TRIALS

Top Ten Major Publications: Mount Sinai Cardiac Cath Lab

1. Kini A, Marmur J, Kini S, Dangas G, Wallenstein S, Cocke T, Brown E, Ambrose J, Sharma S. Creatine Kinase-MB elevation 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. *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 are common after otherwise successful PCI and are not associated with any higher mortality at 12-15 months follow-up. We also established by careful follow-up, that patients with elevated CK-MB but declining value can safely be discharged home without any untoward events.

2. Moreno P, Purushothaman K, Fuster V, Echeverri D, Trusczyńska H, Sharma S, O'Connor William. Plaque neovascularization is increased in ruptured atherosclerotic lesions of the human aorta: Implications for plaque vulnerability. *Circulation* 110: 2032, 2004.

Clinical Implications: We are the pioneers in making the observation that one of the mechanisms of plaque rupture is mediated by new vessel formation in the adventitia and is exaggerated in diabetic patients and in lesions with high lipid contents.

3. Sharma S, Ahsan C, Lee J, Kim M, Fisher E, Steinhamer A, Kini A. 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. *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%) at 15 months of follow-up.

4. Agarwal A, Kini A, Attanti S, Lee P, Ashtiani R, Steinheimer A, Moreno P, Sharma S. Results of repeat balloon valvuloplasty for treatment of aortic stenosis in patients aged 59 to 104 years. *Am J Cardiol* 95:43, 2005.

Clinical Implications: While aortic valve replacement (AVR) is a standard treatment for symptomatic aortic stenosis (AS), many elderly patients are high risk for AVR and functionally limited by AS. In these patients, opening the aortic valve by percutaneous balloon procedure (BAV) and repeating up to three times if needed, can provide effective symptomatic improvement for 3-5 years with low complication rates.

5. Sharma S, Tamburino F, Mares A, Kini A. Improved outcome with AngioJet thrombectomy during primary stenting in acute myocardial infarction patients with high-grade thrombus. *J Invasive Cardiol* 18:8C, 2006.

Clinical Implications: To establish good TIMI flow and microvascular myocardial perfusion in patients with large thrombus burden in the setting of AMI can be safely achieved by mechanically removing thrombus by the AngioJet thrombectomy catheter prior to stenting. In this series of 145 patients, use of AngioJet decreased MACE rates with a trend towards improved survival at one-year follow-up.

6. Wu C, Hannan E, Walford G, Ambrose J, Holmes D, King S, Clark T, Katz S, Sharma S, Jones R. A risk score to predict in-hospital mortality for percutaneous coronary interventions. *J Am Coll Cardiol* 47:654, 2006.

Clinical Implications: By interrogating a large NY State PCI database, independent factors influencing in-hospital mortality were identified with creation of a simple riskscore from 0-40 predicting in-hospital mortality from 0.05 to 99% after PCI. A simple handout for calculating PCI risk-score has been generated for use in daily clinical practice.

7. Solomon R, Natarajan M, Doucet S, Sharma S, Staniloae C, Katholi R, Gelormini J, Labinaz M, Moreyra A and the Investigators of the CARE study. Cardiac angiography in renally impaired patients (CARE) study: A randomized double-blind trial of contrast-induced nephropathy in patients with chronic kidney disease. *Circulation* 115:650, 2007.

Clinical Implications: The prevailing notion that Iodixanol (Visipaque), an iso-osmolar contrast agent is superior to other non-ionic contrast agents (based on the NEPHRIC study) were evaluated against Iopamidol (Isovue) in this largest multi-center randomized trial of 414 pts with chronic renal insufficiency (CRI). The trial showed that Iopamidol is as effective as Iodixanol in preventing CIN in CRI patients and showed a significantly lower post PCI serum creatine rise in diabetic pts especially receiving pre-treatment with N-acetylcysteine (Mucomyst).

8. Kunamneni P, Rajdev S, Krishnan P, Moreno P, Kim M, Sharma S, Kini A. Outcome of intracoronary stenting after failed maximal medical therapy in patients with symptomatic myocardial bridge. *Cathet Cardiovasc Intervent* 71:185, 2008.

Clinical Implications: This report showed that coronary stenting for treatment of intra-myocardial bridge is associated with high adverse cardiac events at follow-up of 2.5 yrs and hence should be avoided. In rare, extremely refractory cases, DES for intra-myocardial bridge should only be used as a last resort.

9. Rajdev S, Krishnan P, Irani A, Kim M, Moreno P, Sharma S, Kini A. Clinical application of prophylactic percutaneous left ventricular assist device (TandemHeart) in high-risk percutaneous coronary intervention using an arterial pre-closure technique: single-center experience. *J Invasive Cardiol* 20:67, 2008.

Clinical Implications: PCI in patients with severe LV dysfunction (LVEF <20%) and/or high-risk coronary anatomy (single vessel supplying the heart, unprotected left main) poses special challenge and could be risky, and use of TandemHeart (taking blood from LA to Femoral artery) for LV assistance in these high-risk patients may help to decrease procedural morbidity and mortality. In this series of 24 high-risk patients, use of TandemHeart followed by femoral artery Pre-close technique was associated with no procedural complications and excellent long-term outcome. Six of these patients had LVEF in single digit (<10%).

10. Kini A, Chen V, Krishnan, P, Kim M, Suleman J, Mares A, Moreno P, Sharma S. Bolus-only vs. Bolus + infusion of Glycoprotein IIb/IIIa inhibitors during percutaneous coronary intervention. *Am Heart J* 156:513, 2008.

Clinical Implications: While GP IIb/IIIa inhibitors are routinely used to improve PCI outcomes, their use is associated with higher vascular and bleeding complications. We reported that infusion of GP IIb/IIIa inhibitors after PCI could safely be eliminated (give bolus only), with decreasing vascular and bleeding complications yet maintaining anti-ischemic benefit up to 12 months follow-up.

Mount Sinai Heart Cardiac Cath Lab is committed to advancing our field through participation in clinical research trials and the publication of major clinical research.

Top Ten Key Clinical Trials:

Study Title	Study Details	Sponsor	PI	Target Enrollment & Study Sites	Current Status/ Enrollments
FREEDOM Trial	Randomized trial comparing CABG vs. PCI in diabetic with multivessel disease. To evaluate whether PCI with DES is more or less effective than the existing standard of care CABG. Multicenter, two-arm, open label prospective randomized superiority trial with equal allocation of 3 yrs duration	National Heart, Lung and Blood Institute (NHLBI)	S. Sharma	2,058 (Global)	Ongoing/60 subjects enrolled. 28PCI/ 32CABG
IMPELLA PROTECT II Trial	PROTECT II: A prospective, multi-center randomized controlled trial of the IMPELLA® RECOVER® LP 2.5 System versus intra-aortic balloon pump (IABP) in patients undergoing non-emergent high risk PCI	ABIOMED	S. Sharma	650 (USA)	Ongoing/ 16 subjects enrolled
XIENCE V Registry	XIENCE™ V Everolimus Eluting Coronary Stent System (EECSS) USA post-approval study	Abbott Vascular	S. Sharma	5,000 (USA)	Ongoing/ 133 subjects enrolled
ABCD-PCI Trial	Early ambulation and discharge VS. overnight hospital stay for patients undergoing successful vascular closure after PCI	St. Jude Medical MSSM	M. Kim	600/6 sites (USA)	Ongoing/ 200 subjects enrolled
VWF STUDY	To determine if BAV and AVR is effective at reversing the acquired Type 2- vWF syndrome seen in severe AS. Deficient vWF and Factor-VIII complex is responsible for bleeding	MSSM	J. Bander	100 Single Center MSSM	Ongoing/ 47 subjects enrolled

Study Title	Study Details	Sponsor	PI	Target Enrollment & Study Sites	Current Status/ Enrollments
ASPIRIN-RESISTANCE Study	A randomized pilot trial for aggressive therapeutic approaches in aspirin resistant patients undergoing PCI	MSSM	A. Kini	36 Single Center MSSM	Completed/ 36 subjects enrolled
TAXUS V Trial	TAXUS V: A randomized, double-blind trial to assess TAXUS Paclitaxel-Eluting Coronary Stents	Boston Scientific	S. Sharma	1,171 (USA)	Completed/ 6 subjects enrolled
PROSPECT Trial	An IVUS imaging study with virtual histology in patients with unstable atherosclerotic lesions to predict future cardiac events from non-culprit artery in ACS pts	Guidant	P. Moreno	700 (USA)	Completed/ 3 subjects enrolled
PLATO Trial	A randomized, double-blind, parallel group, Phase 3, efficacy and safety study of AZD6140 compared with Clopidogrel for prevention of vascular events in patients with non-ST or ST elevation Acute Coronary Syndromes (ACS) [PLATO – A Study of PLATelet inhibition and Patient Outcomes]	AstraZeneca	A. Kini	18,000 (Global) 5,000 (USA)	Completed/ 2 subjects enrolled
SKS-PRECISE Trial	A randomized pilot trial for treatment of true bifurcation lesions with simultaneous kissing stents. SKS technique vs. conventional technique	Cordis, J&J	S. Sharma	100 Single Center MSSM	Completed/ 100 subjects enrolled

PATIENT SUCCESS STORIES

Patient: Walter Drew, 82-year-old male

Diagnosis: Right and left coronary artery blockages

Treatment: Staged rotational atherectomies and insertion of drug-eluting stents

“I’ve always been a very physical person,” Walter Drew begins. “I like to play golf and do things outdoors. But over the last several years I sensed I was really slowing down. About two years ago I had an incident – chest pains and so on – that took me to my community hospital in Connecticut for an angiogram. Lo and behold, I was told that my right coronary artery was all blocked up. But no doctor there wanted to touch it. Just live with it they said.”

“I thank Dr. Sharma for doing what others wouldn’t do and for pulling it off with no complications whatsoever. Pretty amazing.”



This non-approach didn’t sit well with Walter Drew and when he chanced to read an article about Dr. Sharma’s low complication rate in *Businessweek*, Drew called Mount Sinai’s Catheterization Lab director. “Dr. Sharma said he had a device like a Pac-Man that could fix my blockage. That was good enough for me. I made an appointment and my wife and I drove down to New York in late August 2008 to get it done.”

“Everything went extremely well,” Drew reports. “Dr. Sharma cleared my clogged right artery and put in a stent to keep it open. About as fast as I could get to the hospital and home again, I was feeling much better.”

“But before I was released, Dr. Sharma surprised me by saying that my left coronary artery was also in bad shape and that I should come back in a month and have that one done too.”

So back Walter Drew went in September for an atherectomy and stenting of the left coronary artery.

“Now I’m feeling strong enough to get my golf clubs out again,” says Drew cheerfully. “I have to admit

that I’m still a bit slower than I want to be, but at 82, I guess I can’t complain. I thank Dr. Sharma for doing what others wouldn’t do and for pulling it off with no complications whatsoever. Pretty amazing.”

Patient: Eugene Gilhooley, 57-year-old male

Diagnosis: Right coronary artery blockage

Treatment: PCI of right coronary artery and insertion of drug-eluting stents

“My journey to Mount Sinai’s cath lab and Dr. Sharma began with a visit to Dr. Gavani, my heart doctor,” Gene Gilhooley explains. “I hadn’t had a check-up in years and I didn’t really have any symptoms that worried me except for a certain amount of shortness of breath. I just figured that at my age I probably should find out what was going on.”

Dr. Gavani ran a number of tests on Gene, and explained that the root of the problem was ischemia. Dr. Gavani told her patient, “The best guy to take care of your problem – to open up the blockages to your heart – is Samin Sharma in Manhattan.” “She said I shouldn’t waste any time getting down there,” Gene continued.

Patient Gilhooley was not happy about the advice. Taking time off from his work as a plumbing contractor was not easy, but on the day after Christmas he presented himself to the Mount Sinai Cath Lab.

“Dr. Sharma didn’t waste any time getting things done,” says Gene admiringly. “First he did what he called a diagnostic catheterization. He snaked a tube up through an artery in my groin and did an angiogram, finding the blockage right away. He went back in a second time with some new tools to open up the artery and insert two stents.” The whole procedure was done in a matter of minutes and the patient went home the same day.

“Dr. Sharma’s the best,” comments Gene a few months later. “I was back at work in a few days and ever since that scare I’ve been eating right, taking my medications, going to the gym, and doing my best to stay on the right track. I figure I owe it to him as well as to me. And the surprising thing is that once I put my mind to it, taking better care of myself hasn’t been that hard.”



“I was back at work in a few days and ever since that scare I’ve been eating right, taking my medications, going to the gym, and doing my best to stay on the right track.”

Patient: Paul Pellman, 93-year-old male

Diagnosis: Acute myocardial infarction, CHF and cardiogenic shock

Treatment: Complex PCI of left main artery using rotational atherectomy & DES



"Now, about the only thing I'm not able to do is run the marathon. Dr. Sharma is a terrific guy."

Paul Pellman arrived at Mount Sinai's Cath Lab by ambulance on January 12th, 2009. He was in cardiogenic shock and was being kept alive on an intraaortic balloon pump. Dr. Sharma, who had been informed of the emergency, was already prepped to begin treatment immediately.

"The problems started a long time before," Paul Pellman relates, "I was an ex-smoker with asthma and was under treatment for high cholesterol and PAD, among other things. My cardiologist had sent me to South Nassau Hospital after I had an incident of breathing difficulties. They gave me my original catheterization, and discovered my coronary artery disease had progressed to the point that it was causing my heart to work harder and become enlarged. He said it might be fixable, and recommended that Dr. Sharma do the job. I went back home to think about it."

Unfortunately, Paul's condition was rapidly deteriorating and a couple of days later he was back at South Nassau. "I'm told that my heart was barely pumping when I got there," Pellman reports, "so they hooked me up to a machine and sent me almost immediately into the city, where Dr. Sharma was ready for me."

Sharma and his cath team moved quickly to unblock several segments of Pellman's left arteries and to insert four non-eluting stents to keep them open in the future. It was a complex intervention that required entering both branches of the arteries leading from the left ventricle. In both instances the calcified lesions on the interior arterial walls were scored and compressed by means of rotational atherectomy using a catheter tipped with a cutting balloon.

"I suffered no complications and was able to go home in a couple of days," says patient Pellman with amazement. "Now, about the only thing I'm not able to do is run the marathon. Dr. Sharma is a terrific guy."

Patient: Richard Kaplan, 49-year-old male

Diagnosis: Chronic totally occluded right coronary artery

Treatment: Complex PCI including rotablator after CTO recanalization and insertion of DES

In September 2007 Richard Kaplan found himself in the ER at Robert Wood Johnson Hospital with a heart attack. “I had blockages in three major arteries. In two separate procedures they catheterized and stented the two left arteries, but the third artery, which was 100% closed, they were only willing to do as a bypass operation,” reports Kaplan. “open surgery at my age scared me, so I decided to wait,” he continues. But then last June, the patient began to feel some soreness in his chest and thought he might be having another MI.

Back in the local hospital, Kaplan was given a diagnostic catheterization, which revealed that both of his left arteries were holding up fine but that new smaller vessels had begun to grow above and below the blockage on the right coronary artery. “The pressure this created was like trying to suck on a tiny straw,” Kaplan explains. “My cardiologist told me I needed to do something and if I wouldn’t go for bypass surgery I should contact Dr. Sharma. ‘He’s the guru who does what other doctors wouldn’t consider.’”

Kaplan made an appointment with Dr. Sharma. “He did some tests and then said ‘Sure, I can do that. No problem.’ The subsequent procedure took about an hour and a half, since it was so complicated. I went home and in a few days I was feeling strong. I went back to work immediately after the holiday. Now I have another fully operating artery, feel no pain, and have lots more energy.”

Of Dr. Sharma, Kaplan adds, “I can’t praise him and his staff enough. They use the most modern technology to perform the impossible. And then they check in frequently – I must have had three calls already to see how I’m doing and make sure I’m taking my medicines. I know how lucky I am and I’m doing everything right now.”

“I can’t praise him and his staff enough. They use the most modern technology to perform the impossible.”



Patient: Grace Vogel, 92-year-old female

Diagnosis: Non-STEMI with 95% occlusion left main coronary artery and cardiogenic shock on IABP

Treatment: Rotational Atherectomy followed by insertion of drug-eluting stents

"Their quiet efficiency, technical expertise, compassion and caring patience, made all the difference at a time when I was stressed beyond belief."



"My elderly mother had been coping with a host of symptoms relating to chronic heart failure for years," explains daughter Margaret Vogel. "Last November her difficulty breathing reached a crisis and she ended up in South Nassau Community Hospital. Dr. Jerome Zisfein diagnosed her with acute heart failure, pulmonary edema and severe blockages in her heart arteries and veins. He told my mother that because of her age and history he was not equipped to help beyond prescribing some medication that would extend her life a few months."

"My mother is not one to give up easily," Vogel continues. "She's very sharp and she probed the doctor for options. He allowed that he could ask Dr. Samin Sharma at Mount Sinai whether he'd take her case. Dr. Zisfein said Sharma was known for taking on high-risk cases that others did not want. Without a moment's hesitation, my mother asked that arrangements be made. Dr. Zisfein made a call, sent over the results, and within a few hours Mom was transferred to Mount Sinai's Cath Lab in Manhattan."

"By the time I got there," the daughter added, "work on my mother was already under way – less than three hours later she was done. Dr. Sharma emerged from the procedure gleeful. 'Everything went very well,' he told me.

'Before she was 100% blocked. Now she's got two stents and is 100% unblocked! She should be around to vote in the next election!'"

Margaret Vogel summed up the experience. "I am so grateful to Dr. Zisfein for referring my mother to Mount Sinai. I have no doubt that she wouldn't be alive today if it weren't for the extraordinary skills of Dr. Sharma and his entire staff. Their quiet efficiency, technical expertise, compassion and caring patience, made all the difference at a time when I was stressed beyond belief. As for my mother, she can't thank him enough."

Patient: Hector Paniagua, 53-year-old male

Diagnosis: Acute myocardial infarction with right coronary occlusion

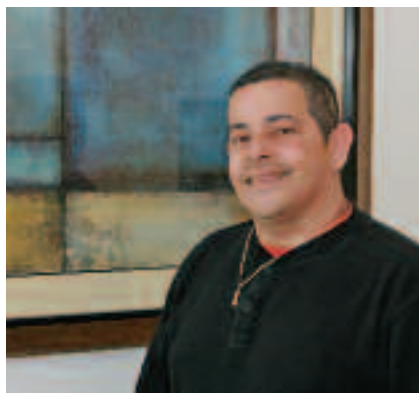
Treatment: PCI of right coronary artery, thrombectomy, and insertion of non-drug eluting stent

Hector Paniagua was just coming off the basketball court after a game with his sons and nephews when he felt a crushing pain in his chest. “I was sweating, much more than when I usually play,” he remembers. “And I was shivering. I waited a couple of minutes thinking the pain and chills would pass, but they just got worse. I told the kids I was going next door to my niece’s to lie down.”

Hector’s wife arrived to find him drenched and pale and suggested he go to the hospital, but he insisted on going to their apartment a few blocks away. Once there, things got much worse and she called 911. In less than ten minutes an ambulance was there, and the paramedics told him that he was having a heart attack. They took Hector straight to Mount Sinai, less than a dozen blocks away.

“The X-ray they took showed a huge clot in one of my arteries. They called upstairs for Dr. Kini and she told them she’d meet me in the Cath Lab,” Hector continues. “She explained what was going to happen – before I knew it they had made an incision in my leg, worked their way up to the blood clot, opened up the blood flow, and put in a stent. Right away I could feel the pain and pressure going away. When they wheeled me out to recovery there was my family waiting. And I was back to laughing and joking.”

Hector stayed in the hospital for another two days. Once home he went right back to work. “This experience was a real awakening,” he says. “I’ve changed my eating habits, I’m losing weight, my sugar levels are down to near normal, and I’ve stopped smoking. I feel so good I plan to live another 53 years. I am so lucky that Dr. Kini was there when I needed her. She’s an incredible doctor.”



“I am so lucky that Dr. Kini was there when I needed her. She’s an incredible doctor.”

KEY STAFF BIOGRAPHIES



Samin K. Sharma, MD, FSCAI, FACC

Zena & Micheal A. Weiner Professor of Medicine Cardiology
Director Cardiac Cath Lab & Intervention

Education and Training

MBBS: SMS Medical College Jaipur, India
Residency, Internal Medicine: New York University Downtown Hospital
Fellowship, Cardiology: City Hospital Center at Elmhurst
Fellowship, Interventional Cardiology: Mount Sinai Hospital

Clinical Interests

Coronary Artery Disease,
Interventional Cardiology,
Valvuloplasty

Dr. Samin K. Sharma is well known for complex coronary interventions, performing over 1,500 interventions a year (highest in the country) while achieving an extremely low complication rate. According to the reports of the New York State Department of Health, he has the highest success rate of angioplasty (lowest mortality <0.2%) in the entire group of interventional cardiologists in New York State since 1994. Dr. Sharma is widely published on topics of rotational atherectomy, newer interventional devices and drug eluting stents, as well as on the ways to reduce various complications of coronary intervention by use of beta-blockers, GP IIb/IIIa inhibitors and appropriate techniques for the coronary interventional devices. He has been regularly featured on national and state TV channels and in various newspapers and magazines such as *Newsday*, *Newsweek*, *New York Times*, *New York Post*, *Forbes*, *Wall Street Journal*, *Barron's*, *Daily News*, *Washington Post*, *New York Resident*, *New York Sun*, *New York Magazine*, *Earthtimes*, *India Abroad*, and *India Today*. He has been continuously featured in the *America's Top Physicians* (by Castle Connolly and consumers council) and *New York's Best Doctors & New York's Super Doctors* listing and in national *Who's Who*. Dr. Sharma also has passion for teaching and fellows learn every day with his expertise and have awarded him the Simon Dack best teacher in cardiology division in 2000. Dr. Sharma also serves on the Cardiac Advisory Board of the New York State for coronary interventions that advises the health department on issues of health policies and supervision, safety and appropriateness of the heart care by various hospitals in New York. For his unprecedented success and outcome of angioplasty for last ten years, New York State Governor George Pataki awarded Dr. Sharma the 'Governor's Excellence Award' on May 23, 2006. He is also the recipient of 'Physician of the year' award given by MSH nurses and 'Jacobi Medallion Physician' award given by MSH physicians, in 2007.

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Annapoorna S. Kini, MD, MRCP, FACC

Associate Professor of Medicine, Cardiology
Director Interventional Cardiology Fellowship
Associate Director Cardiac Cath Lab & Intervention

Education and Training

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

Dr. Annapoorna Kini performs over 1,000 coronary interventions annually (the highest number by a female interventionalist in the United States) with an extremely low complication rate of <0.3%. She is highly regarded for performing the complex coronary interventions in advanced heart disease patients with utmost safety and excellent long-term results. She has become the national expert on heart assist devices, including Tandem Heart and Impella, which are crucial for many of these high-risk cases. Dr. Kini also specializes in the non-coronary interventions of mitral and aortic balloon valvuloplasty, and alcohol septal ablation for obstructive hypertrophic cardiomyopathy. 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.

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Pedro R. Moreno, MD, FACC

Associate Professor of Medicine, Cardiology
Director Interventional Research, Cardiac Cath Lab

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 performs over one thousand cardiac coronary invasive procedures annually (including diagnostic catheterizations, angioplasties and coronary stents) with >99% success rate and <1% major complications. Dr. Moreno is triple board certified in Internal Medicine, Cardiology, and Interventional Cardiology. As a world-renowned expert in atherosclerosis, Dr. Moreno has been a pioneer in the understanding of inflammation and acute coronary syndromes. Dr. Moreno was the first to describe the role of macrophages in living patients with unstable angina and acute myocardial infarction in 1993. Its impact in the scientific community was evident by the immediate recognition, which opened new routes of investigation around the world.

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Clinical Interests

General Cardiology,
Interventional Cardiology,
Hypertrophic Cardiomyopathy



Clinical Interests

Cardiac Catheterization,
Coronary Angioplasty/Stenting,
Vulnerable Plaque Imaging



Michael C. Kim, MD, FACC

Assistant Professor of Medicine, Cardiology
Director Coronary Care Unit

Education and Training

MD: Georgetown University School of Medicine
Residency, Internal Medicine: Mount Sinai Hospital
Fellowship, Cardiology: Mount Sinai Hospital
Fellowship, Interventional Cardiology: Mount Sinai Hospital

Dr. Michael C. Kim currently performs over 1,000 diagnostic catheterization procedures and over 650 percutaneous coronary interventions annually. He has quickly developed an outstanding clinical reputation within the tri-state area and boasts a superb safety record. Dr. Kim serves as both Director of the Coronary Care Unit and Director of Medical Education in the Cardiac Catheterization Laboratory at Mount Sinai Heart. As Director of the Coronary Care Unit, Dr. Kim is recognized as an expert in the management of critical care cardiology especially in the area of acute coronary syndromes and ischemic heart failure.

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Clinical Interests

Coronary Artery Disease,
Interventional Cardiology,
Cardiac Catheterization



Prakash Krishnan, MD

Assistant Professor of Medicine, Cardiology
Director Endovascular Intervention, Cath Lab

Education and Training

MBBS: Rajah Muthaih Medical College, India
Residency, Internal Medicine: St. Vincent's CMC of NY
Fellowship, Cardiology: Ochsner Foundation Hospital
Fellowship, Interventional Cardiology: Mount Sinai Hospital

Dr. Prakash Krishnan performs over 1,500 procedures annually (including diagnostic coronary and peripheral angiograms and complex coronary and endovascular interventions) in his short time with the department, with a major complication rate of 0.1% and success rate of over 98%. Dr. Krishnan is a leader in endovascular intervention in New York City. He is an expert at catheter based vascular therapy techniques with balloon angioplasty, stenting, atherectomy, cryoplasty, and laser of all vascular beds including the carotid, vertebral, subclavian, renal mesenteric, iliac, femoral and tibial arteries. Interventionalists from across the country visit Mount Sinai regularly to learn endovascular techniques from Dr. Krishnan.

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Clinical Interests

Peripheral Artery Disease,
Angiography,
Endovascular Intervention

Barry A. Love, MD, FRCPC

Assistant Professor of Pediatrics, Cardiology
Director Pediatric Cardiac Cath Lab

Education and Training

MD: University of Western Ontario
Residency, Pediatrics: Children's Hospital of Montreal
Fellowship, Pediatric Cardiology: Children's Hospital Boston

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

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Clinical Interests

Pediatric Catheterization
& Interventions,
Pediatric and Adult Congenital
Heart Diseases

Sean P. Pinney, MD

Assistant 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 Hospital, Boston
Fellowship, Cardiology: Columbia-Presbyterian Medical Center

Dr. Sean Pinney is a well-known cardiologist specializing in the management of patients with advanced heart failure. Together with Dr. Anelechi Anyanwu, Dr. Pinney established Mount Sinai's ventricular assist device program which now 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 thoracic committee for the United Network of Organ Sharing (UNOS) and is a member of the medical advisory board for the New York Organ Donor Network.

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Clinical Interests

Cardiac Catheterization
Cardiac Transplantation
Heart Failure

VOLUNTARY/PART-TIME FACULTY



Master Teacher

Jose Meller, MD

Clinical Professor Medicine, Cardiology

Education and Training

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

Clinical Interests

Clinical Cardiology, Fellows' Education, Cardiac Catheterization

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Javed Suleman, MD

Associate Clinical Professor Medicine, Cardiology

Education and Training

MBBS: Sindh Medical College, Pakistan
Residency, Internal Medicine: Salem Hospital
Fellowship, Cardiology: Worcester Medical Center
Fellowship, Interventional Cardiology: Mount Sinai Hospital

Clinical Interests

Clinical Cardiology, Cardiac Catheterization, Coronary Intervention

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Mazullah Kamran, MD

Associate Professor Medicine, Cardiology
Director Cardiac Cath Lab, Elmhurst Hospital

Education and Training

MD: Albany Medical College
Residency, Internal Medicine: University of Pittsburgh
Fellowship, Cardiology: North Shore University Hospital at Manhasset
Fellowship, Interventional Cardiology: Mount Sinai Hospital

Clinical Interests

Clinical Cardiology, Fellows' Education, Cardiac Catheterization

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Johnny Lee, MD

Associate Clinical Professor Medicine, Cardiology

Education and Training

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

Clinical Interests

Clinical Cardiology, Non-invasive Cardiology, Coronary Interventions

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Paul S. Lee, MD

Associate Professor Medicine, Cardiology

Education and Training

MD: University of Minnesota

Residency, Internal Medicine: Mount Sinai Hospital

Fellowship, Cardiology: Mount Sinai Medical Center

Fellowship, Clinical Heart Failure and Molecular Cardiology: University of Toronto

Clinical Interests

Clinical Cardiology, Biostatistics, Interventional Cardiology

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Nitin Barman, MD

Clinical Instructor Medicine, Cardiology

Education and Training

MD: University of Chicago

Residency, Internal Medicine: University of California - San Francisco

Fellowship, Cardiology: Cleveland Clinic Foundation

Fellowship, Interventional Cardiology: Mount Sinai Hospital

Clinical Interests

Clinical Cardiology, Non-invasive Cardiology, Interventional Cardiology

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Sameet Palkhiwala, MD

Clinical Instructor Medicine, Cardiology

Education and Training

MD: New York Medical College

Residency, Internal Medicine: St. Vincent's Medical Center

Fellowship, Cardiology: St. Vincent's Medical Center

Fellowship, Interventional Cardiology: Mount Sinai Hospital

Clinical Interests

Clinical Cardiology, Endovascular Interventions, Coronary Interventions

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Robert Pyo, MD

Clinical Instructor Medicine, Cardiology

Education and Training

MD: University of Illinois

Residency, Internal Medicine: Elmhurst Hospital

Fellowship, Cardiology: Mount Sinai Hospital

Fellowship, Interventional Cardiology: Mount Sinai Hospital

Clinical Interests

Clinical Cardiology, Cardiac Catheterization, Coronary Interventions

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Anthony Shih, MD

Clinical Instructor Medicine, Cardiology

Education and Training

MD: State University of New York at Buffalo
Residency, Internal Medicine: Hospital of the University of Pennsylvania
Fellowship, Cardiology: Mount Sinai Hospital
Fellowship, Interventional Cardiology: Mount Sinai Hospital

Clinical Interests

Clinical Cardiology, Endovascular Interventions, Coronary Interventions

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Srinivas Kesanakurthy, MD

Assistant Clinical Professor Medicine, Cardiology

Education and Training

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

Clinical Interests

Clinical Cardiology, Cardiac Catheterization, Coronary Interventions

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Robert A. Zaloom, MD

Assistant Clinical Professor Medicine, Cardiology

Education and Training

MD: Ross University
Residency, Internal Medicine: Lutheran Medical Center
Fellowship, Cardiology: SUNY Downstate Medical Center

Clinical Interests

Clinical Cardiology, Echocardiography, Cardiac Catheterization

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George Fernaine, MD

Assistant Clinical Professor Medicine, Cardiology

Education and Training

MD: SUNY, Health Science Center
Residency, Internal Medicine: St. Vincent's Hospital
Fellowship, Cardiology: St. Vincent's Hospital
Fellowship, Interventional Cardiology: Lenox Hill Hospital

Clinical Interests

Clinical Cardiology, Cardiac Catheterization, Coronary Interventions

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Farah E. Atallah-Lajam, MD

Associate Clinical Professor Medicine, Cardiology

Education and Training

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

Clinical Interests

Clinical Cardiology, Cardiac Catheterization, Coronary Interventions

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William J. Schwartz, MD

Assistant Clinical Professor Medicine, Cardiology

Education and Training

MD: Albert Einstein College of Medicine
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, Non-invasive Cardiology, Cardiac Catheterization

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Choudhury Hasan, MD

Assistant Clinical Professor Medicine, Cardiology

Education and Training

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

Clinical Interests

Cardiac Catheterization, Coronary Interventions, Echocardiography

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Jose Wiley, MD

Assistant Professor Medicine, Cardiology

Director Cath Lab, North General Hospital

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

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Lynne Glasser, MD

Assistant Professor Medicine, Cardiology

Director Interventional In-Patient Service

Education and Training

MD: SUNY Health Science Center

Residency, Internal Medicine: New York University Medical Center

Fellowship, Cardiology: Manhattan Veterans Administration Medical Center

Since joining Mount Sinai Medical Center in November 2008, Dr. Glasser is playing an important role in the treatment and management of interventional patients, before and after the procedure.

Clinical Interests

Clinical Cardiology, Preventive Cardiology

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Beth Oliver, RN

Senior Director of Nursing

Education and Training

BS, Nursing: UMass Boston

Nurse Practitioner Certification: Columbia University

Beth Oliver MS BSN is the Senior Director of Nursing for Mount Sinai Heart. In this role she is responsible for the supervision as well as management of a large complex staff, which consists of NPs, RNs, PCAs and BAs. Beth has been Nursing leader in Cardiac services for the past 20 years and has been involved in several publications, abstracts and presentations. She is the past recipient of the Ellen Fuller award of excellence in Nursing Leadership 2003 and a member of Sigma Theta Tau, the national Nursing Honor Society, AONE (American organization of Nurse Executives) and the board of Directors at the American Heart Association. Beth works closely with the entire Mount Sinai Heart team to create a center of clinical excellence.

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Rosario Marasigan, RN

Clinical Nurse Manager

Education and Training

BS, Nursing: Philippine Women's University

Rosario Marasigan is the clinical nurse manager since 2006 and has worked very effectively and efficiently in managing a very complex Cath Lab schedule of more than 130 staff members.

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Gregory Gojkovich

Operations Manager

Education and Training

AA degree, Moorpark College, California.

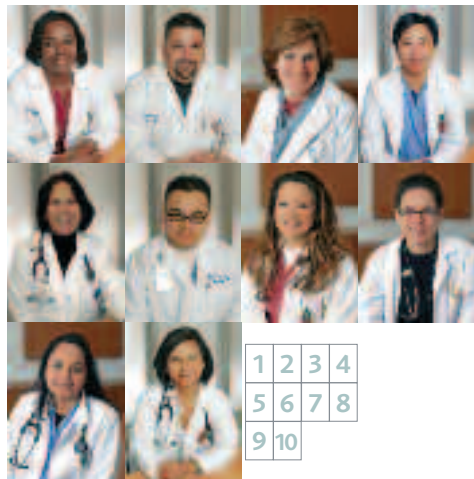
Greg Gojkovich joined the Mount Sinai Cath Lab in January 1987. In 1992, he accepted a Cath Lab Operational Manager position at Beth Israel Medical center, New York, NY. Returning to Mount Sinai in 2001, he is currently the Operations Manager of Mount Sinai Heart.

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Cardiac Cath Lab Nurse Practitioner Team

- 1 – Caroline Austin-Mattison, NP
- 2 – Nicholas Demetriou, NP
- 3 – MaryBeth Duffy, NP
- 4 – Haydee Garcia, NP
- 5 – Leticia Jakasal, NP
- 6 – Rheoneil Lascano, NP
- 7 – Gloria Manzanilla, NP
- 8 – Melissa Mattimore, NP
- 9 – Surekha Patel, NP
- 10 – Antoniette Tolentino, NP



Interventional Database Team

(left to right):

Delenia Gulle, Rucha Karajgikar,
Roja Thapi, Angelica Mares,
Madhavi Jakkula



Cardiac Cath Lab Research Team

(left to right):

EJ Fernandez, Attila Filipovich,
Kameswari Vallabhajosyula,
Eyal Levy, Michael Fusilero



2009 LIVE SYMPOSIUM OF COMPLEX CORONARY & CARDIOVASCULAR CASES JUNE 17-20, 2009

The fields of interventional cardiology and endovascular interventional therapy continue to evolve with the rapid growth of available established and new technologies and therapies. To remain at the forefront of care, interventionalists must continually make changes to appropriately treat coronary, valvular and peripheral vascular disease based on the most effective available devices and trial results – continuing educational activities are vital to continued success. The issue of experience and cost-effectiveness of a new technology or technique always needs to be weighted before implementing it into an established practice.

The Complex Coronary and Cardiovascular Cases Symposium provides concise and current information through live cases, brief lectures on the fundamentals of interventional cardiovascular medicine, and panel discussions with distinguished international faculty, to expand your already-firm knowledge base.

For more information on the symposium, including faculty, special events, key dates and registration, visit www.cccsymposium.org.

SPECIAL FOCUS ON CALCIFIED, BIFURCATION & TOTAL OCCLUSION LESIONS

HIGHLIGHTS

- **Complex High-Risk Cases**
- **Peripheral & Renal Interventions**
- **Unprotected Left Main**
- **Chronic Total Occlusion**
- **Septal Ablation**
- **Distal Protection Devices**
- **Valvuloplasty**
- **PFO/ASD Closure**
- **Percutaneous Valve Replacement**

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Michael Kim, MD
Prakash Krishnan, MD
Pedro Moreno, MD

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The Cardiac Catheterization Lab
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highest quality of diagnostic
and interventional cardiac
care to patients through
procedural excellence,
education and research.