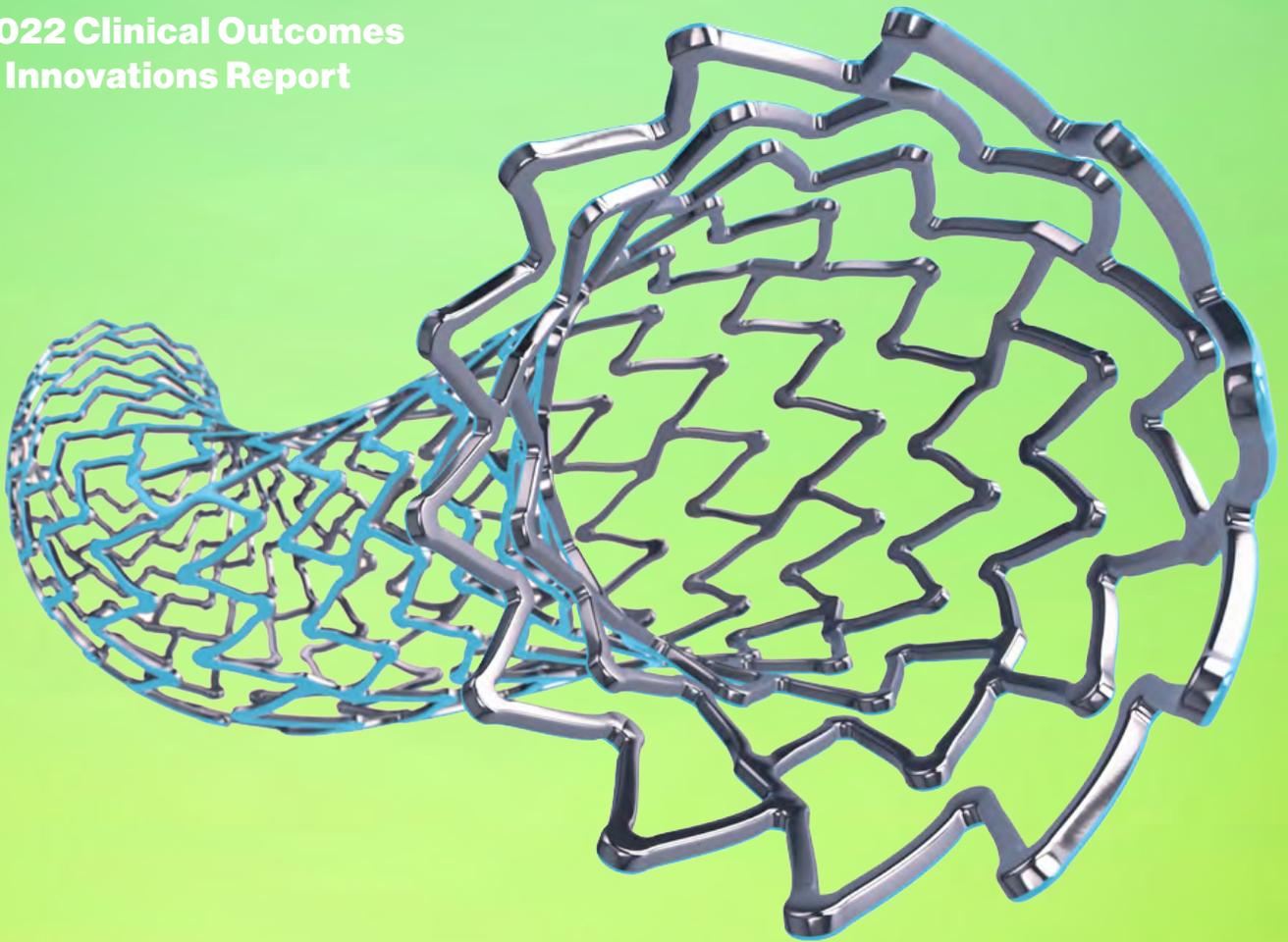


DR. SAMIN K. SHARMA FAMILY FOUNDATION

Cardiac Catheterization Laboratory

**2022 Clinical Outcomes
& Innovations Report**





Samin K. Sharma, MD, FACC, MSCAI

Director, Cardiovascular Clinical Institute
Senior Vice-President, Operations
& Quality, Mount Sinai Heart
Director, Interventional Cardiology,
Mount Sinai Health System
President, Mount Sinai Heart Network



Annapoorna S. Kini, MD, MRCP, FACC

Director, Cardiac Catheterization Laboratory
Interventional Director, Structural Heart
Disease, Mount Sinai Health System
Director, Interventional Cardiology
Fellowship Program

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

We are proud to present this 2022 edition of our *Clinical Outcomes & Innovations Report*. For more than 11 years, we've been compiling this report of our procedural outcomes and volume, transparently sharing our results as compared to other centers in our region and across the country. The landscape of interventional cardiology is changing constantly with the main goal of improving patient outcomes.

At The Mount Sinai Hospital, our Cardiac Catheterization Laboratory remains a leader for several reasons, including the:

- Talent of our team of interventionalists and supporting staff, who all work together and respect each other;
- Strict adherence to proven updated protocols and standards of care;
- Innovation and implementation of new technologies and techniques, including participation in numerous clinical trials that can benefit our patients;
- Heart team approach, which involves consulting with our colleagues in clinical cardiology and cardiac surgery to ensure the best course of care for each complex patient;
- Compassion and genuine concern for our patients' health, long after their procedure.

Our procedural outcomes data over the years support the statement that we have *perfected the art of PCI*. As a result, many patients who have been considered too high risk to receive care elsewhere are referred here and go home with a successful outcome and an improved quality of life.

Patients remain at the center of everything we do. In this publication, you will read the words of our grateful patients, many of whom had particularly challenging clinical scenarios. We will continue to pioneer new paths, setting the pace for another remarkable year of innovation and excellence in 2023. We will continue to improve our patient clinical and procedural outcomes by constantly analyzing our results critically and making new advances.

“Many patients who have been considered too high risk to receive care elsewhere are referred here and go home with a successful outcome and an improved quality of life.”

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For more information, visit www.mountsinai.org/interventional-cardiology-cath-lab



Valentin Fuster, MD, PhD, MACC

Physician-in-Chief,
The Mount Sinai Hospital
President, 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

President, Mount Sinai Heart

In the right hands, technology can be transformative. Advances like cardiac catheterization and PCI were transformative technologies for cardiology. But early on, the team at the Cardiac Catheterization Laboratory at The Mount Sinai Hospital understood that technology by itself doesn't move us forward—innovation happens when new technology comes together with vision, teamwork, and dedication to improvement.

Since I started at The Mount Sinai Hospital in 1983, the pace of innovation has only increased. Today's Cardiac Catheterization Laboratory employs a full armamentarium of approaches to address almost any issue with the heart and peripheral vessels. Samin K. Sharma, MD, and Annapoorna S. Kini, MD, and their ambitious teams are not only opening occlusions and preventing myocardial infarctions (MI), they're also repairing damaged valves, correcting congenital deformities, and helping patients avoid heart failure.

With all these innovations, the patient remains at the center of everything that happens here. Innovation isn't just about developing, testing, implementing, and deploying the latest devices with our partners. At Mount Sinai Heart, innovation involves improving the patient experience, with close attention to patient satisfaction scores and constant adjustments to our processes to make things smoother and more pleasant. It also means developing mobile applications that can help get our STEMI patients into treatment faster, or helping interventionists at other institutions find the best approach for the types of complex lesions we routinely address at The Mount Sinai Hospital.

In the *2022 Clinical Outcomes & Innovations Report*, we feature some of our latest innovations, along with several case studies of patients who have enjoyed successful outcomes after experiencing varying levels of cardiac complexities. We hope you enjoy this update of our activities.

“At Mount Sinai Heart, innovation involves improving the patient experience, with close attention to patient satisfaction scores and constant adjustments to our processes to make things smoother and more pleasant.”



David L. Reich, MD

President, The Mount Sinai Hospital
and Mount Sinai Queens

“When it comes to community outreach, the Cardiac Catheterization Laboratory has forged relationships with providers in communities that might traditionally have more limited access to the treatments available at The Mount Sinai Hospital.”

President, The Mount Sinai Hospital

The mission of the Mount Sinai Health System is to provide compassionate patient care with seamless coordination and to advance medicine through unrivaled education, research, and outreach in the diverse communities we serve.

The work that happens at the Mount Sinai Cardiac Catheterization Laboratory encapsulates those values perfectly. At The Mount Sinai Hospital, we treat more than 15,000 cardiac patients each year, returning them to their families with a success rate greater than 99 percent.

The accounts of patients’ positive experiences throughout these pages demonstrate compassionate patient care—with glowing praise not just for their successful outcome, but for the compassion and attention to detail demonstrated by everyone on the team.

Seamless and smooth coordination of care at Mount Sinai Heart starts at admission, moving on to procedure and then to follow-up. But it also happens outside our walls. Our Cardiac Catheterization Laboratory works to engage our referring physicians and emergency medical services as part of the process, communicating as much as possible to shave valuable minutes from transfer times and get patients into treatment as soon as possible.

Our commitment to research and education is reflected in the important role of our interventional fellows, who learn the entire process at the hand of experienced interventional cardiologists and the hundreds of papers published in prestigious journals each year.

When it comes to community outreach, the Cardiac Catheterization Laboratory has forged relationships with providers in communities that might traditionally have more limited access to the treatments available at The Mount Sinai Hospital and provides access to the latest care through our own clinic at the hospital.

As our Health System continues to grow, Samin K. Sharma, MD, and Annapoorna S. Kini, MD, and their colleagues are helping to share their expertise with colleagues throughout the Mount Sinai Health System, sharing innovations and expertise to bring the best cardiac care to all New Yorkers.

We hope you enjoy reading this *Cardiac Catheterization Laboratory Clinical Outcomes & Innovations Report* and welcome your feedback on our progress.

The Cardiac Catheterization Laboratory at The Mount Sinai Hospital

An Overview of Services and Outcomes



From Left — Isha Ranadive, MD; George Dargas, MD, PhD; Amit Hooda, MD; Vishal Kapur, MD; Jeffery Bander, MD; Samin K. Sharma, MD; Parasuram Melarcode Krishnamoorthy, MD; Raman Sharma, MD; Annapoorna S. Kini, MD; Gregory Serrao, MD; Joseph M. Sweeny, MD; Prakash Krishnan, MD; Sahil Khera, MD; Pedro Moreno, MD

“If you are working on something that you really care about, you don’t have to be pushed. The vision pulls you.”

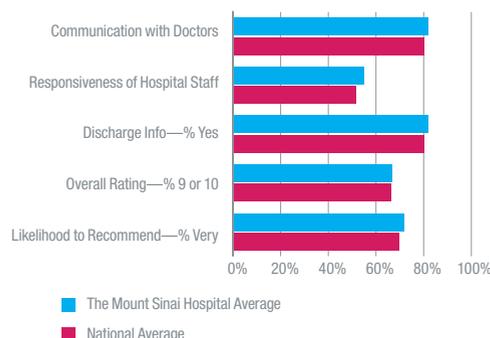
- STEVE JOBS
Late Apple CEO



The Cardiac Catheterization Laboratory at The Mount Sinai Hospital is among the highest-volume centers, yet also among the safest interventional catheterization laboratories in the United States. Each member of the Cardiac Catheterization Laboratory staff has a strong work ethic and takes pride in his or her contribution to the principal goal: delivery of efficient and safe care to patients in need. As a result, the Cardiac Catheterization Laboratory consistently reports a high level of patient satisfaction; 64 percent of patients are discharged on the same day after their successful interventional procedure.

The system of established standard protocols, rigorous attention to details, and a strong sense of teamwork have helped us to achieve the best interventional outcomes in the country. Overall angiographic success of non-CTO lesions remains over 99 percent in our Cardiac Catheterization Laboratory. We continue to improve our outcomes every year, maintaining low procedural complications in 2022. This remarkably low complication rate has been achieved despite high complexity and comorbid medical conditions of patients treated in the Cardiac Catheterization Laboratory.

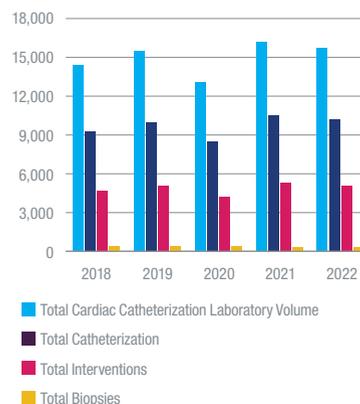
PATIENT SATISFACTION: 2021–2022 HCAHPS SURVEY



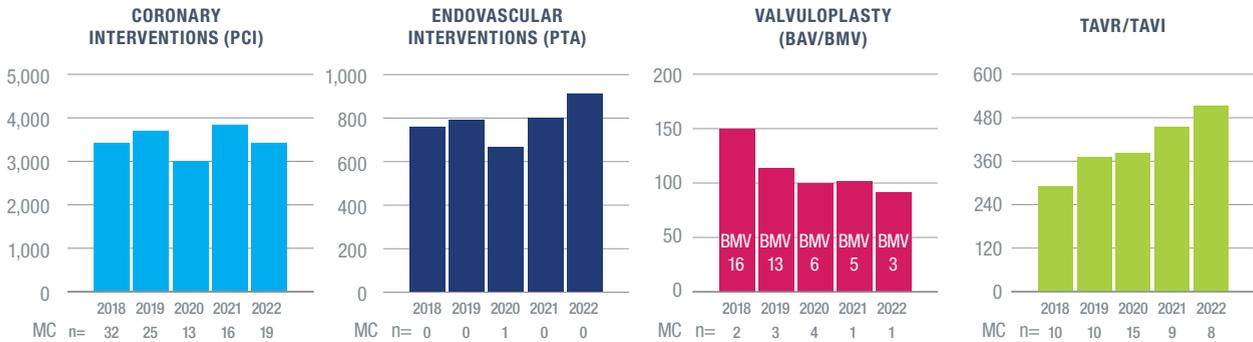
64 Percent

OF OUR ELECTIVE INTERVENTIONAL PATIENTS ARE DISCHARGED ON THE SAME DAY OF THE PROCEDURE

CARDIAC CATHETERIZATION LABORATORY VOLUME AT THE MOUNT SINAI HOSPITAL PROCEDURES OVER THE LAST FIVE YEARS



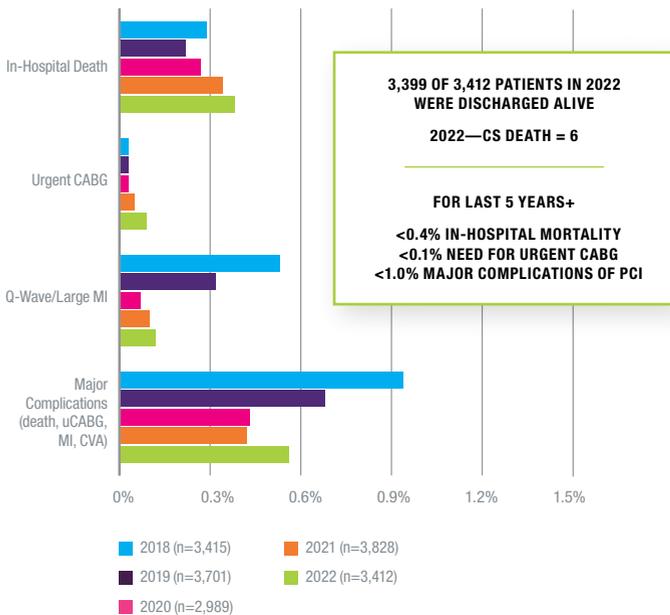
INTERVENTIONAL VOLUME AND MAJOR COMPLICATIONS (MC) 2018–2022



2022

Septal Ablation = 16 TMVR = 10 TTVR = 0 LAAO = 3
 MitraClip = 61 TriClip = 6 PFO/ASD Closure = 39

SAFETY OF PCI: TEMPORAL TRENDS IN COMPLICATIONS AT THE MOUNT SINAI HOSPITAL



25 Percent of 3,412

CASES HAD A PLAQUE MODIFICATION STRATEGY BEFORE STENT IMPLANTATION DUE TO LESION COMPLEXITY

36 Percent

OF PCIs AND 46 PERCENT OF DIAGNOSTIC CATHS WERE DONE VIA RADIAL ACCESS

Comparison of The Mount Sinai Hospital Interventional Outcomes With New York State Data: 2018–2022

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

Reports of risk-adjusted PCI mortality rates (RAMR) have consistently placed The Mount Sinai Hospital Cardiac Catheterization Laboratory or its interventionalists among the lowest for in-hospital and 30-day risk-adjusted mortality, receiving the double star denoting statistically significantly lower RAMR than the statewide average consistently over the last 23 years of New York State Department of Health PCI reporting.

NYS Reports also showed that 30-day risk adjusted readmission rate post-PCI have been statistically lower than statewide average being double star notation (**) for last 5 consecutive reports.



NYS-DOH REPORT OF PCI 2018 DATA ON THE TOP 10 VOLUME CENTERS IN NY STATE 30-DAY RAMR

PCI Statistics 2018	# Cases	All Cases	Non-Emergency Cases
1. The Mount Sinai Hospital	3,348	0.92	0.56
2. Saint Francis Hospital	2,823	1.12	0.81
3. North Shore University Hospital	2,334	0.85**	0.47**
4. NYU Hospitals Center	2,099	0.98	0.60
5. Columbia Presbyterian Hospital	2,098	1.42	1.15
6. Saint Joseph's Hospital	2,012	1.28	0.77
7. Lenox Hill Hospital	1,759	0.73	0.55
8. Mount Sinai Beth Israel	1,458	0.81	0.53
9. Buffalo General Medical Center	1,397	1.36	0.64
10. Stony Brook University Hospital	1,333	1.88	1.23
NYS Total	51,435	1.38	0.87

www.nyhealth.gov

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

MSH VS NY STATE PCI CASES, 30-DAY RISK-ADJUSTED READMISSION RATES (RARR) TO 2018

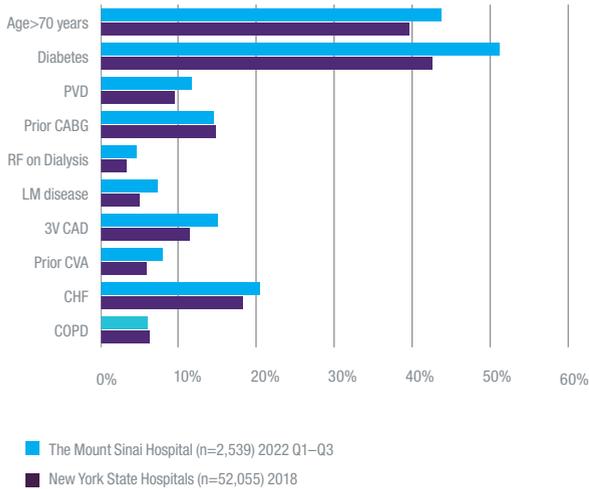
Hospital	# Cases	30-Day Readmission	All Cases RARR%	95% CI for RARR
1. The Mount Sinai Hospital	2,661	178	6.83**	(5.86, 7.91)
NYS Total	45,956	4,150	9.03	

www.nyhealth.gov

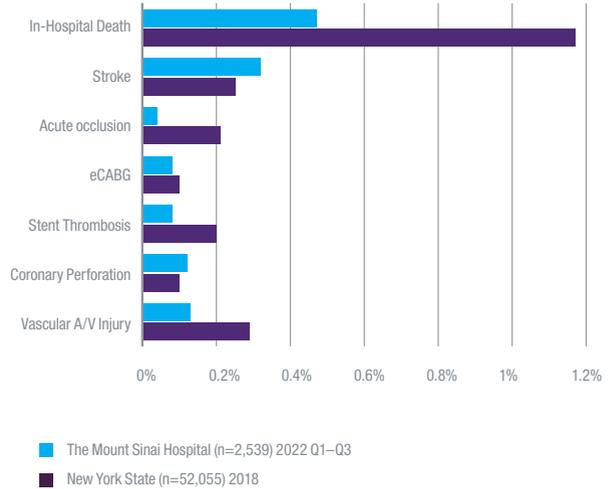
**Risk-adjusted readmission rate significantly lower than NY statewide rate

Samin K. Sharma, MD, Annapoorna S. Kini, MD, Prakash Krishnan, MD, the Cath Lab NPs, and Interventional Fellows.

IMPORTANT BASELINE CLINICAL AND LESION CHARACTERISTICS OF PCI:
 NY STATE HOSPITAL DATA 2018–2022 Q1–Q3



NYS-REPORTED MAJOR PCI COMPLICATIONS



15,000+ Cases Per Year

LED BY FIVE SENIOR FULL-TIME INTERVENTIONALISTS,
 WHO TOGETHER PERFORM MORE THAN 9,500 CASES PER YEAR.

23 Consecutive Years

THE MOUNT SINAI CARDIAC CATHETERIZATION
 LABORATORY RECEIVES PRESTIGIOUS
 TWO-STAR RATING FOR PCI IN NY STATE.



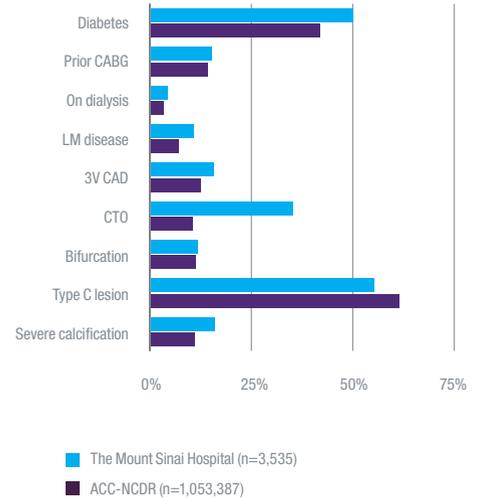
Comparison Of The Mount Sinai Hospital Interventional Outcomes With Other U.S. Hospitals: 2022 R4 Q2 ACC-NCDR Reports

The American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR) reports the characteristics and in-hospital outcomes after PCI of more than 1,400 hospitals in the United States, providing data of >1 million patients annually.

On these pages are the important baseline and procedure characteristics of The Mount Sinai Hospital (MSH) versus ACC-NCDR hospitals. These graphs show superior outcomes despite higher complexities for PCI patients at The Mount Sinai Hospital in comparison to other U.S. hospitals in the ACC-NCDR report for 2022R4Q2.

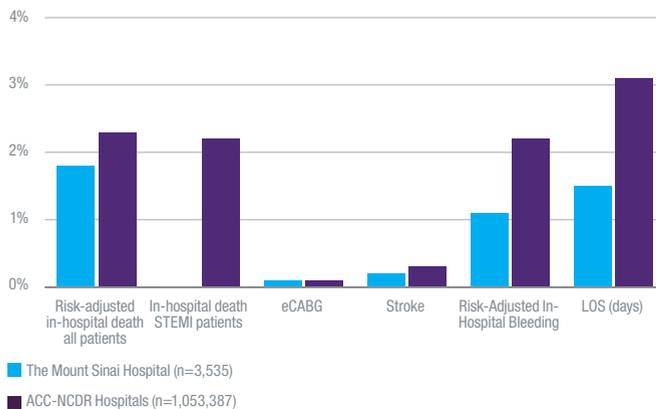
At Mount Sinai, we have established evidence-based protocols for proper evaluation of CAD patients before scheduling catheterization and possible intervention. We follow a rigorous application of the appropriate use criteria (AUC) of the American College of Cardiology and fractional flow reserve (FFR/iFR) guiding the decision-making for appropriately indicated PCI.

IMPORTANT BASELINE CLINICAL AND LESION CHARACTERISTICS OF PCI: ACC-NCDR DATA FOR 2022R4Q2



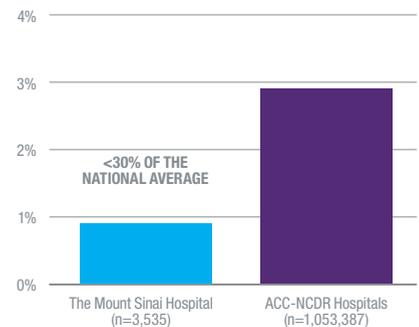
PCI COMPLICATIONS:

MSH VS. ACC-NCDR HOSPITALS 2021 Q3–2022 Q2



NATIONAL PCI OUTCOME METRICS; MAJOR COMPLICATIONS:

COMPOSITE: PROPORTION OF PCI PATIENTS WITH DEATH, eCABG, STROKE OR eTVR; MSH VS. ACC-NCDR (N=1,600 HOSPITALS) FOR 2021 Q3–2022 Q2



Complex High-Risk Percutaneous Coronary Interventions (PCI)

SAMIN K. SHARMA, MD, AND ANNAPOORNA S. KINI, MD

Earlier randomized clinical trials have suggested the benefits for coronary artery bypass graft (CABG) surgery in higher angiographic-complexity cases over percutaneous coronary intervention (PCI). Based on data evidence, there is an increasing tendency at The Mount Sinai Hospital to recommend surgery for patients with more complex coronary artery disease (CAD). Ultimately, the decision to have either surgery or PCI lies with the patient and his or her family, after consultation with the Heart Team, which includes a cardiologist, cardiothoracic surgeon, and a cardiac interventionalist. Many patients (≈50 percent) with complex CAD choose revascularization with PCI, due to lower short-term complications and relative ease of recovery compared to surgery. As far as the left main (LM) CAD is

concerned, a recent meta-analysis comparing PCI to CABG, showed similar mortality at 5 years and 10 years after PCI vs CABG but higher myocardial infarction (MI) and repeat revascularization after CABG.

The FAME-3 Trial compared FFR-guided PCI with CABG in three vessel coronary artery disease and found PCI to be inferior to CABG overall but better in low Syntax Score patients.

Based on the current data and practice guidelines, the following patient groups will benefit more with CABG vs. PCI:

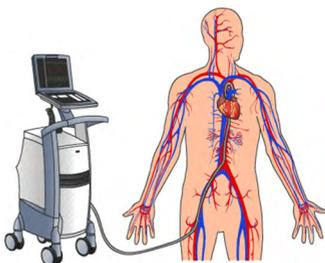
- Three-vessel CAD and SYNTAX Score >32
 - Diabetics with three-vessel CAD or complex two-vessel CAD with prox-mid LAD lesion
 - Left main ± additional vessel CAD with SYNTAX Score >32
- In addition to expertise in

Based on data evidence, there is an increasing tendency at The Mount Sinai Hospital to recommend surgery for patients with more complex coronary artery disease (CAD).

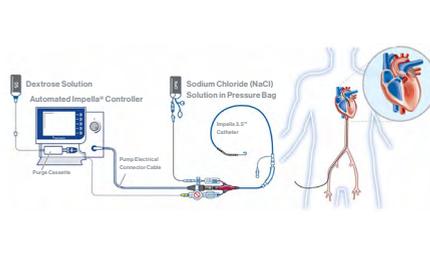
interventional treatment of complex CAD, our Catheterization Laboratory serves as a tertiary center for complex coronary intervention (bifurcation, calcified, left main, CTO, and/or vein graft lesions) and patients with low ejection fraction (LVEF <35 percent).

We use a variety of adjunct interventional techniques in these complex coronary cases, such as atherectomy (25 percent of lesions) and thrombectomy/distal protection devices (2 percent for thrombotic and vein graft lesions). In a small number of complex lesion patients (≈5 percent of PCI) many of the patients have reduced ejection fraction (LVEF <35 percent), we use LV assist devices such as IABP, Impella or ECMO CardioHelp to safely and dependably perform these high-risk PCIs (Protected PCI).

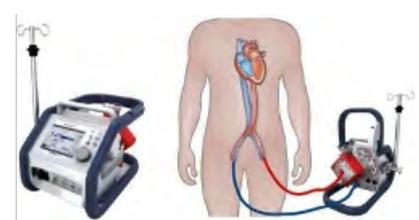
IABP SYSTEM



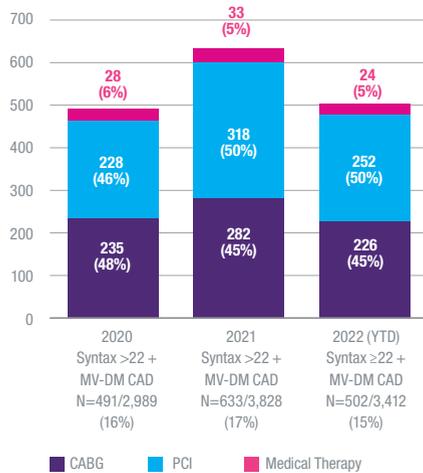
IMPELLA SYSTEM



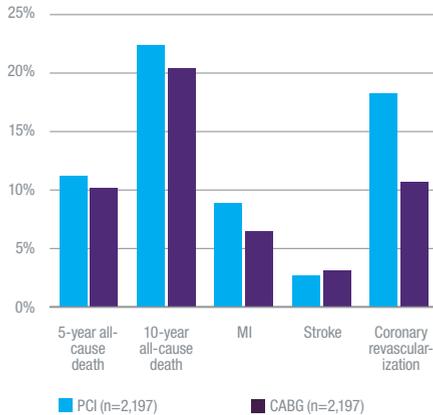
ECMO CARDIOHELP SYSTEM



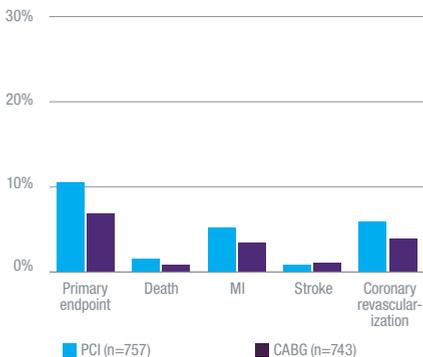
**REVASCUARIZATION CHOICES FOR COMPLEX CAD
(HIGH SYNTAX SCORE AND/OR MV DIABETES):
MSH DATA 2020–2022**



CLINICAL OUTCOMES PCI DES VS. CABG IN LM CAD



FAME 3 TRIAL: CLINICAL OUTCOMES AT ONE YEAR



Norman Sohn, MD

Diagnosis: 1-Vessel CAD

Treatment: Complex PCI, rotational atherectomy and placement of stent



“I cannot adequately express my gratitude to Dr. Sharma for his expertise and for prolonging my life.”

“I was a colorectal surgeon at Lenox Hill Hospital for 40 years. When I was in practice, I always wanted to refer my patients to the place that I thought they would receive the best care. And when it came to cardiac care, I always sent them to Mount Sinai Heart.

“I became a patient in 1997, when I had some heart issues and received great care at Mount Sinai but had no other complications until recently.

“My journey to the Cardiac Catheterization Laboratory began on the evening of Rosh Hashanah. I had been feeling a little sluggish in general, and on that night, I made it to synagogue, but had a hard time getting back. I knew something wasn’t right, so I immediately sought care from a cardiologist. After a series of tests, my doctor referred me to Dr. Sharma for a cardiac catheterization and I was able to get scheduled in just a couple days.

“Dr. Sharma found an almost complete blockage in my LAD which required the use of a special Rotoblator tool, and placement of a stent. He told me had I not received care when I did, I would have had a heart attack. After just a day in the hospital, I left feeling immediately better.

“The care I received at Mount Sinai was superb. I cannot adequately express my gratitude to Dr. Sharma for his expertise and for prolonging my life.”



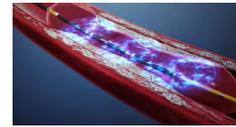
**ROTAPRO ROTATIONAL
ATHERECTOMY SYSTEM (RA)**



**DIAMONDBACK 360 ORBITAL
ATHERECTOMY SYSTEM (OA)**

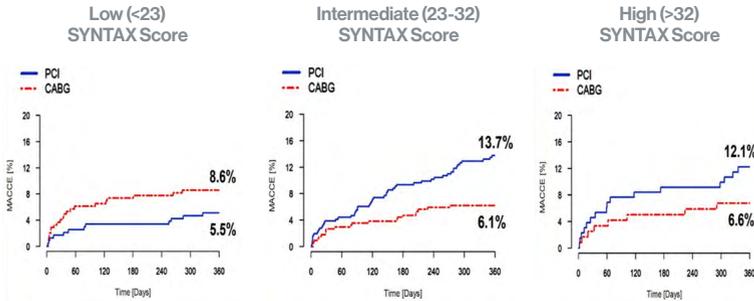


**EXCIMER LASER
ATHERECTOMY SYSTEM (ELCA)**

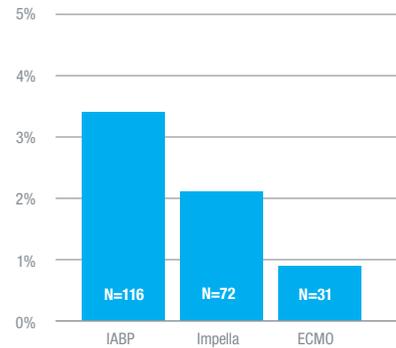


SHOCKWAVE INTRAVASCULAR LITHOTRIPSY (IVL)

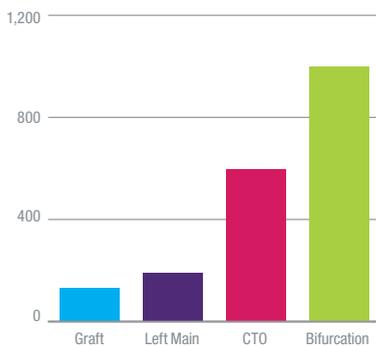
**FAME 3 TRIAL: CLINICAL OUTCOMES
ACCORDING TO SYNTAX SCORE**



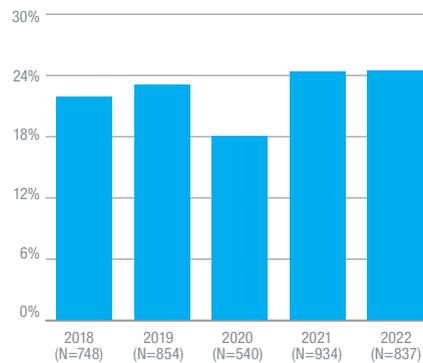
**HIGH RISK PCI WITH LV SUPPORT IN 2022 AT
THE MOUNT SINAI HOSPITAL: (N=3,412 PCIs)**



**COMPLEX CORONARY INTERVENTIONS IN 2022
(N=3,412 PCIs)**



**COMPLEX CORONARY INTERVENTIONS IN 2022—
ATHERECTOMY CASES**

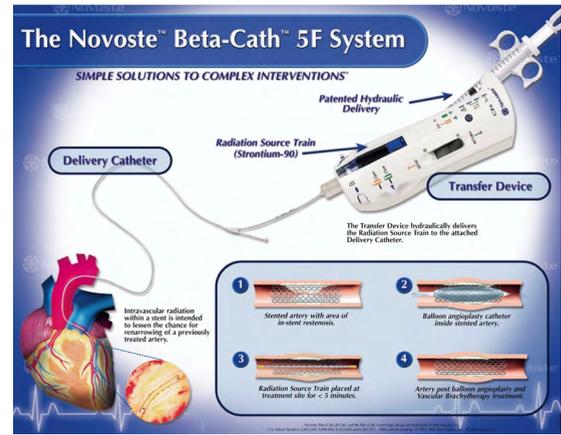


Intravascular Brachytherapy (IVBT) For Multi-Layer Recurrent Des In-Stent Restenosis

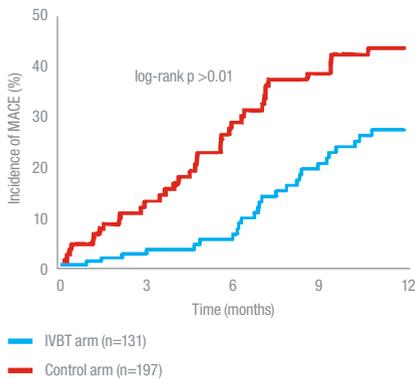
Patients with recurrent in-stent restenosis (ISR) of DES with more than two layers of stents are appropriate cases for IVBT using the Beta-Cath™ System to reduce subsequent restenosis by inhibiting intimal hyperplasia (scar tissue).

Our IVBT data over the last five years have shown excellent acute outcomes with <1 percent major complications (MC), no need for implantation of another stent, and long-term restenosis of <20 percent (compared to 55 percent in comparable recurrent DES ISR without IVBT); reduction by 70% compared to routine treatment.

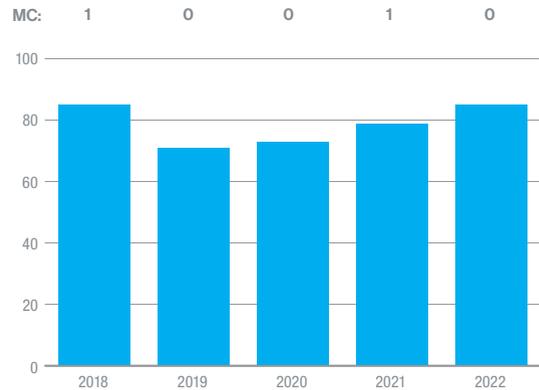
NOVOSTE™ BETA-CATH™ 3.5F SYSTEM



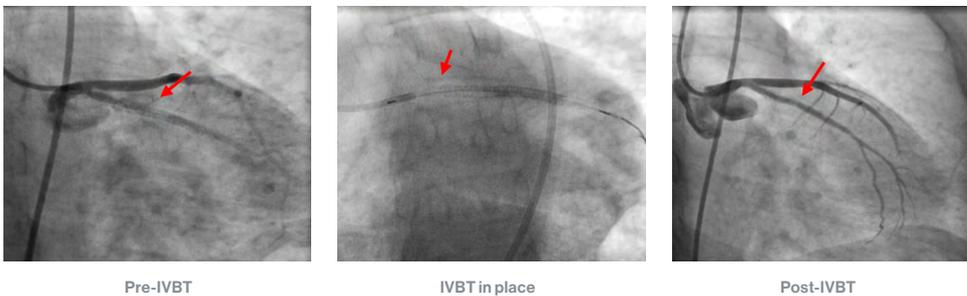
MACE AT ONE YEAR AFTER IVBT + PCI OF RECURRENT DES-ISR: MSH EXPERIENCE



IVBT VOLUME AT THE MOUNT SINAI HOSPITAL



INTRAVASCULAR BRACHYTHERAPY TREATMENT



References

1. Fractional Flow Reserve-Guided PCI as Compared with Coronary Bypass Surgery, *N Engl J Med* 2022;386:128.
2. Percutaneous Coronary Intervention with Drug-Eluting Stents versus Coronary Artery Bypass Grafting in Left Main Coronary Artery Disease: An Individual Patient Data Meta-Analysis, *Lancet* 2021;398:2247.
3. Intravascular Brachytherapy for the Management of Repeat Multi-Layered Drug-Eluting Coronary Stent Restenosis, *Circ Cardiovasc Interv* 2018;11:e00683.

Expanding the Indications of Transcatheter Aortic Valve Replacement (TAVR)

SAMIN K. SHARMA, MD AND ANNAPOORNA S. KINI, MD

Multiple trials of transcatheter aortic valve replacement (TAVR) in patients with varying levels of surgical risk (based on the STS Score) have shown TAVR as a viable therapeutic option for patients who have severe, symptomatic calcific aortic stenosis (AS) at all levels of surgical risk.

The NOTION trial, which compares surgical vs. transcatheter aortic valve replacement in low STS risk patients, showed equivalent results after both strategies. It also showed similar durability of TAVR compared to surgical valve replacement at eight years.

A recent study (PROTECTED TAVR) using the Sentinel Cerebral Protection System (which is an embolic filter designed to trap calcified and thrombotic deposits that become dislodged during the TAVR procedure) has shown that SENTINEL device is associated with a lower risk of disabling stroke but not all strokes compared to the control group.

At our center, the SENTINEL device is now used in about 40% of TAVR cases.

The Mount Sinai Hospital was the first center in the United States to deploy the CoreValve™, in December 2010. Since then, our TAVR volume and outcomes have improved significantly compared with other centers in the Transcatheter Valve Therapy

(TVT) Registry with a 3-Star (★★★) rating according to the STS Registry.

For some AS patients, implanting TAVR has a higher incidence of complications. Hence patients should preferably be referred to open surgical aortic valve replacement (SAVR); currently 20% of AS patients undergo SAVR at The Mount Sinai Hospital.

SAVR will be indicated in the following scenarios of severe AS;

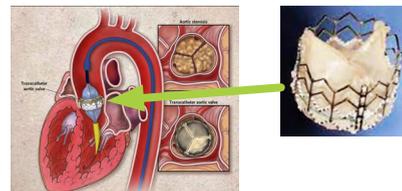
- Age <65 years old
- Low to intermediate STS risk and extensive/complex CAD
- Bicuspid AV with low STS risk
- Concomitant aortic root/aorta dilatation (>4.6cm)
- Heavy LVOT calcification (high chance of annular rupture)
- Low-Intermediate STS risk bioprosthetic dysfunction
- Adverse anatomy (low coronary height, too small or large annulus)
- Concomitant significant MV disease with low surgical risk

After excellent successful TAVR in severe aortic stenosis (AS) patients, TAVR is now being evaluated in moderate aortic stenosis under the FDA approved clinical trial—TAVR EXPAND II Pivotal Trial.

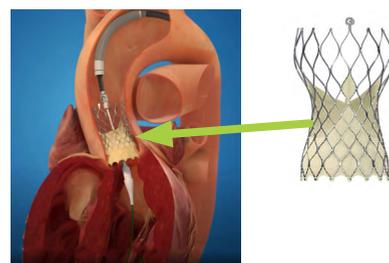
Nationally, TAVR volume has increased every year since 2011, and in 2019, TAVR volume surpassed (↑26%) all forms of AVR surgery concomitant to FDA approval of

TRANSCATHETER AORTIC VALVES FDA-APPROVED DEVICES

SAPIEN



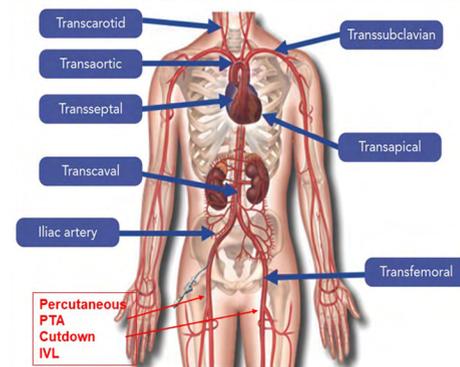
CoreValve™ Evolut™



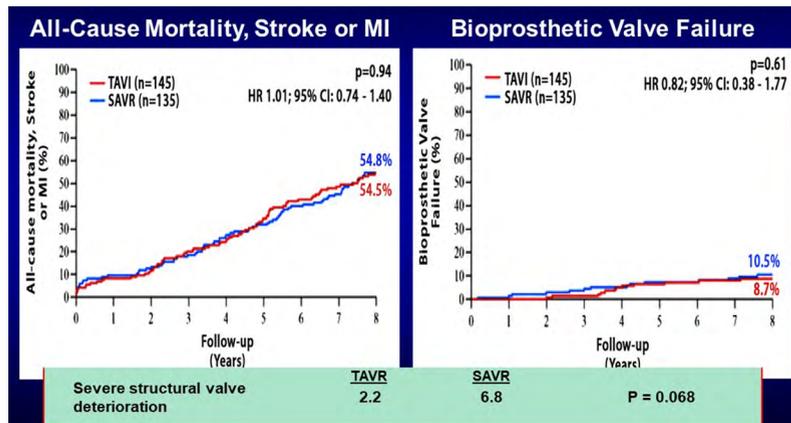
Portico™



OVERVIEW OF APPROACHES FOR TAVR



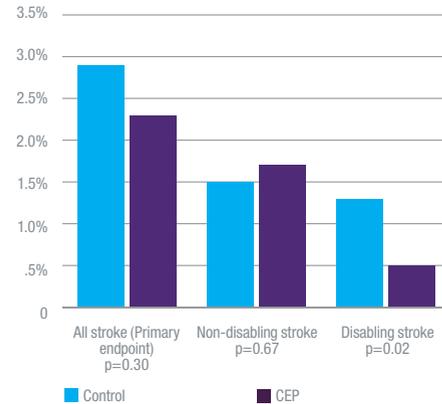
NOTION TRIAL: CLINICAL AND AORTIC BIOPROSTHETIC VALVE FAILURE AFTER 8 YEARS AFTER TAVR VS. SAVR



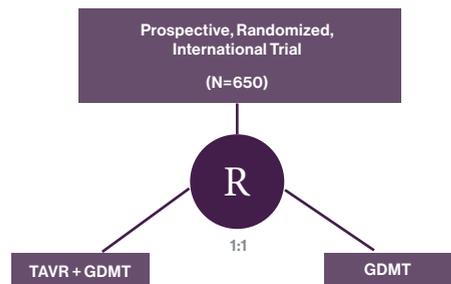
GROWING STRUCTURAL TRANSCATHETER HEART INTERVENTIONS TAVR PROCEDURES AT MSH: 2018 TO 2022



PROTECTED TAVR: STROKE WITHIN 72H/ DISCHARGE (PRIMARY ENDPOINT)



TAVR EVOLUT™ EXPAND II PIVOTAL TRIAL FOR MODERATE AORTIC STENOSIS



Clinical Primary Endpoints: Death, Stroke, BARC 3-4 Bleeding, AKI, Rehospitalization, Re-intervention at 30-day follow up

Primary Effectiveness Endpoints: All-cause Mortality, HF, AVR or Re-intervention at 2 years

The Society of Thoracic Surgeons | **STS/ACC TVT Registry Public Reporting Metrics** | **AMERICAN COLLEGE OF CARDIOLOGY**

Patients with TAVR as of 2021 q3
Hospital 974296

Timeframe First TAVR Procedure Performed	My Hospital TAVR Volume ¹ (Commercial procedures only)		Distribution of Annual Hospital TAVR Volumes (Across all TVT Registry Hospitals)
	Cumulative	Annual volume (Oct 1, 2020 - Sep 30, 2021)	
May, 2012	2353	447	

My Hospital TAVR 30 Day Composite Site Difference ^{1,2,3} (95% Confidence Interval)	Eligible Patients (Oct 1, 2018 - Sep 30, 2021)	Participant Rating	Distribution of Participant Estimates

¹ Missing value (-) indicates that hospital does not meet eligibility criteria for reporting.

² 30 Day Composite consists of six ordered categories based on the worst possible outcome (30-day death) to the best possible outcome (e.g. alive and free of major complications) during hospitalization and the 30-day follow-up period as defined below:

- 30-day death
- 30-day stroke
- 30-day life-threatening or major bleeding
- Acute kidney injury (stage III)
- 30-day moderate to severe paravalvular aortic regurgitation (PVL)
- None of the above

³ The TAVR 30-day mortality/morbidity composite is reported as a "site difference":
 >0 implies "My Hospital" has better than expected performance
 <0 implies "My Hospital" has worse than expected performance

TAVR for low-risk patients.

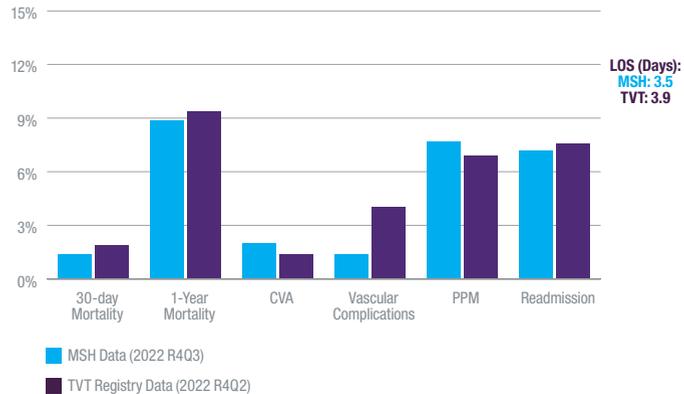
In a report of repeat TAVR versus TAVR explantation from the Centers for Medicare and Medicaid Services (CMS), analysis from a large, nationally representative database showed;

- repeat TAVR was associated with acceptable short-term mortality in a high-risk population.
- repeat TAVR outcomes were superior compared to TAVR explantation at 30 days but not at 1 year.
- repeat TAVR becomes an important option for lifetime management of aortic valve disease.

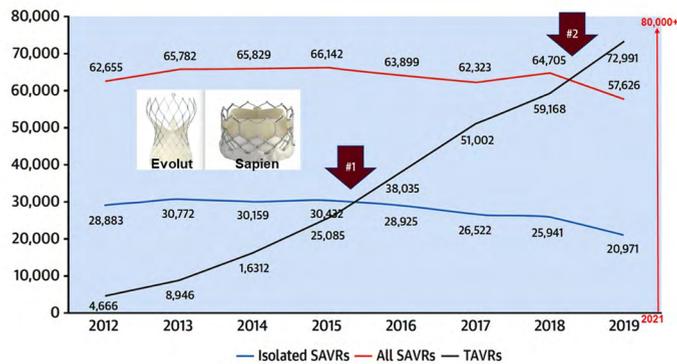
The FDA recently approved the trial of a new system to treat surgery-ineligible patients with severe aortic regurgitation, the Jenavalve Trilogi TAVI system. The Trilogi features three locators that allow the valve to clip onto the native leaflets to enable 100% anchoring thus allowing the device to be fixed and sealed in place once opened therefore avoiding the risk of valve migration and paravalvular leak.

TAVR OUTCOMES AT THE MOUNT SINAI HOSPITAL 2022—N=513

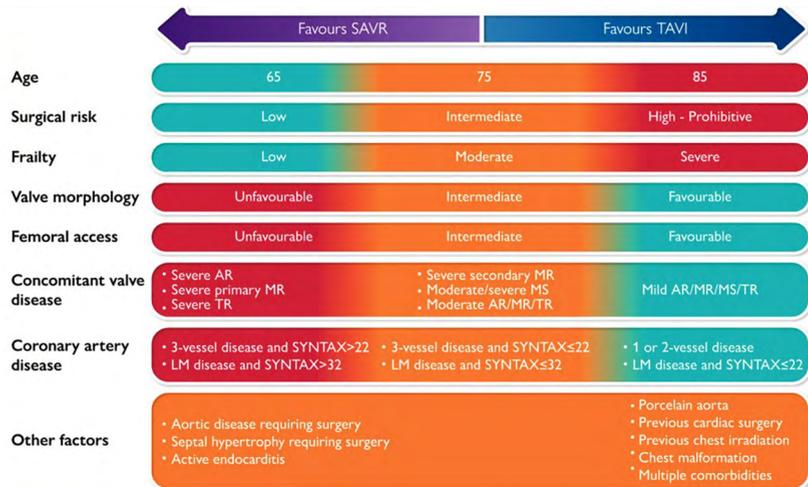
- 62% SAPIEN-3, 38% Evolut-R/Fx CoreValve, 0.2% ACCURATE
- 89.7% Conscious Sedation; 10.3% GA. 38.6% Sentinel
- 92.6% Percutaneous Femoral; 7.2% Cutdown Femoral; 0.2% Carotid, 6.2% ViV (N=32, 27 TAV-in-SAV, 5 TAV-in-TAV)



ANNUAL VOLUMES OF TAVR AND SAVR IN USA



DECISION-MAKING PROCESS BETWEEN TAVR AND SAVR



John Gallarello

Diagnosis: Aortic stenosis and stage 3 heart failure

Treatment: Placement of SAPIEN TAVR device



“The way that they were able to do that without open heart surgery was miraculous.”

“In 2018, I was experiencing some prolonged back pain and wasn't feeling myself, so I visited my primary care physician who ran a few tests, and then suspecting it had something to do with my heart, recommended I go see Dr. Sharma at Mount Sinai.

“I have always been a very active person, I enjoy walks and working in my gardens so I never thought I would be a cardiac patient. I was surprised when Dr. Sharma told me I had a blocked artery and he would need to place two stents. The procedure went amazing—I felt absolutely no pain, and was quickly back to my normal activities.

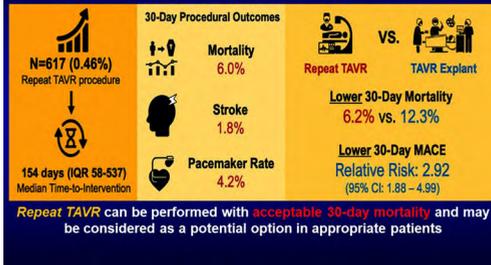
“A few years later, I wasn't feeling myself again, and I went back to Mount Sinai. Dr. Sharma ran a lot of tests to get to the bottom of my issues, it really made me feel well taken care of. It turned out that I was having issues with my aortic valve, which had become stiff and wasn't functioning properly, causing the early stages of heart failure. He told me I was a good candidate for a new procedure that actually could replace my aortic valve through a catheter. Before and after both procedures Dr. Sharma and his team explained everything wonderfully. The way that they were able to do that without open heart surgery was miraculous.

“Everybody was so kind from beginning to end. No one was ever too busy to listen or talk during my stays, and they even packed me a lunch to take home with me the day after my operation.

“I'm a first generation American, my father came to America from Italy and medicine has come such a long way since I was born. I couldn't be more thankful for Dr. Sharma and his team.”

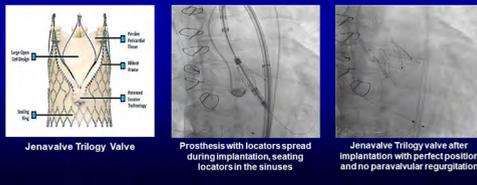
TAV-in-TAV vs TAVR Explant-CMS

Contemporary Repeat TAVR Outcomes in the United States



Jenavalve Trilogy TAVI System

- The Trilogy TAVI System features unique locators that align the THV with the native cusps of the valve and ensures anatomically correct alignment
- The locators “clip” onto the native leaflets, enabling anchoring in pure AR patients with non-calcified valves.



References

- Cerebral Embolic Protection During Transcatheter Aortic-Valve Replacement (PROTECTED TAVR Trial), *N Engl J Med* 2022;387:1253.
- Which Patients with Aortic Stenosis Should Be Referred to Surgery Rather Than Transcatheter Aortic Valve Implantation?, *Eur Heart J* 2022;43:272.
- STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement, *J Am Coll Cardiol* 2020;76:2492.

Strategies to Reduce Stroke After TAVR

SAHIL KHERA, MD, AND ANNAPOORNA S. KINI, MD

Transcatheter aortic valve replacement (TAVR) for aortic stenosis has been the greatest technological advancement in the field of interventional cardiology. Initially intended for high and prohibitive surgical risk patients, TAVR has evolved into a mainstream therapy for management of aortic stenosis. It offers shorter hospital stay, early mobility, and immediate symptomatic improvement in patients suffering from symptomatic severe aortic stenosis. Despite the numerous benefits (compared with conventional open-heart surgery), stroke remains the Achilles heel of TAVR.

Early stroke after TAVR is primarily driven by debris embolization and patient comorbidities. The debris can be calcium, tissue fragments, or thrombus. Comorbidities predisposing to higher stroke rate after TAVR are atrial fibrillation, prior history of stroke, chronic kidney disease, peripheral vascular disease, and frailty. The 30-day stroke rate remains around 4% in randomized clinical trials and

2–2.5% in national registry data. Stroke is associated with worse quality of life and long-term survival.

We at Mount Sinai Structural Heart Program pride ourselves in being one of the highest volume TAVR sites with the lowest stroke rates. This is possible because of our comprehensive neuroprotection strategy. It involves mechanical, pharmacological, and procedural neuroprotection. The Sentinel Embolic Protection Device (Boston Scientific) is a filter that prevents debris from entering the cerebral circulation. It serves as a mechanical neuroprotection for our TAVR patients who are identified to be at the highest risk of procedural stroke. Our strategy is driven by the recent PROTECTED TAVR trial which demonstrated that sentinel embolic protection may help in preventing disabling strokes. In addition, we adhere to meticulous and detailed procedure planning. We also focus on minimizing procedure duration and minimizing anticoagulation interruption for our patients.

Recently, we also published the

We at Mount Sinai Structural Heart Program pride ourselves in being one of the highest volume TAVR sites with the lowest stroke rates.

first well-defined protocol for management of patients with stroke after TAVR. The protocol emphasizes early recognition and timely neurointervention in patients with a clinical disabling stroke and large vessel occlusion. This has led to a dramatic improvement in patient outcomes, reducing stroke morbidity, and facilitating early mobilization and discharge.

Our patients deserve the highest quality structural heart interventions that are evidence driven and focus on improving patient satisfaction and quality of life.

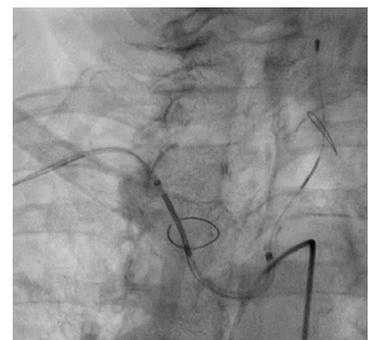


Figure 1: Sentinel Embolic Protection Device being used in a TAVR case.

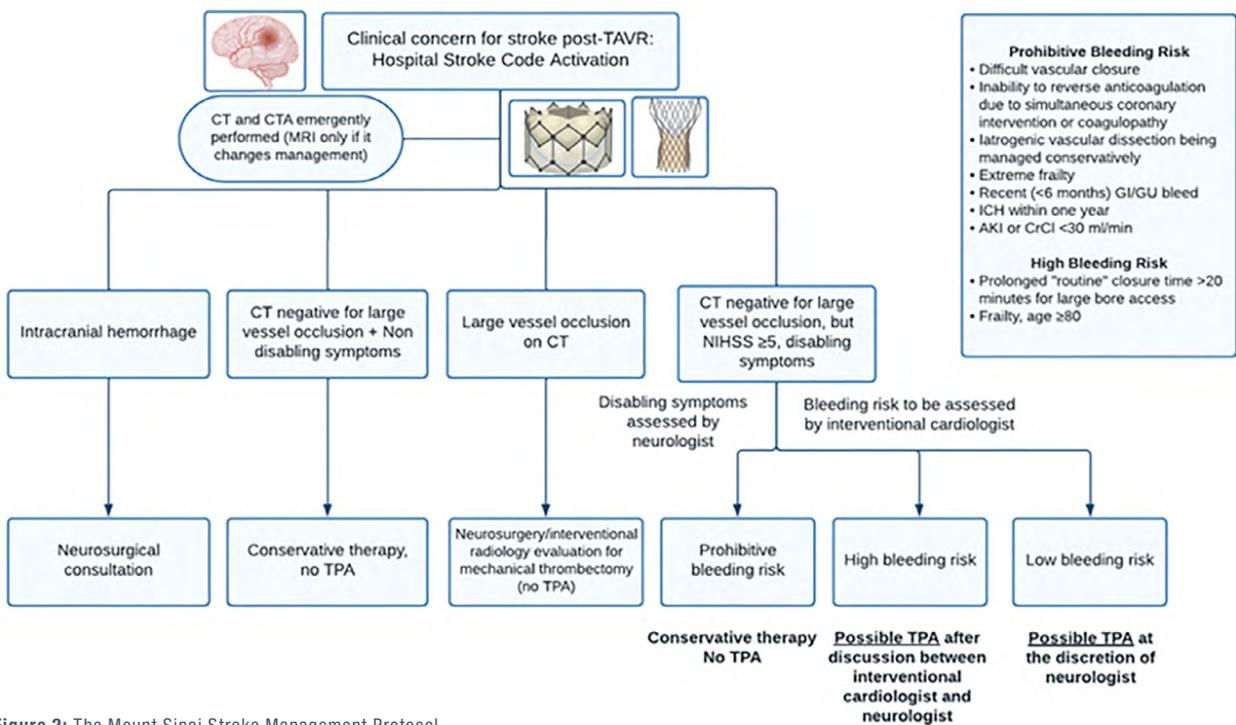


Figure 2: The Mount Sinai Stroke Management Protocol

References

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2. Khera S, et al. Prevention and Management of Stroke after Transcatheter Aortic Valve Replacement – The Mount Sinai Stroke Initiative. In Press.

STEMICathAid Heart Attack Transfer App Update

ANNAPOORNA S. KINI, MD AND ANDRIY VENGRENYUK, MS

Since the launch of the STEMICathAID pilot in July 2021 and throughout 2022, all patients with STEMI at the Mount Sinai Queens Emergency Department have been transferred using the STEMICathAID mobile app developed by the Mount Sinai Cardiac Catheterization Laboratory. This application instantaneously connects the Catheterization Laboratory, Emergency Department, and clinical command center members enabling sharing of EKG, patient

information, and GPS tracking of the ambulance. The design¹ and implementation² of the application have been discussed in prior publications.

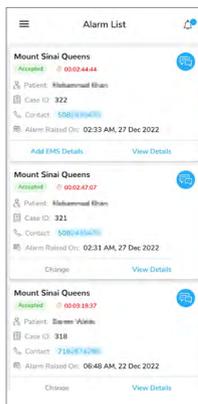
The Mount Sinai Hospital's Cardiac Catheterization Laboratory has previously achieved the American Heart Association (AHA) Mission: Lifeline STEMI registry's Gold Medal for STEMI care. There are many factors that can cause system delays in a large health system, particularly one situated in the most populated

Faster treatment leads to better procedural outcomes and faster recovery with less permanent damage to the heart.

city in the country. Consistently meeting the strict goal of 120 minute door-to-device goal has always been a challenge for us. In a study of 114,871 STEMIs from 648 hospitals participating in the Mission:Lifeline registry, only 17% of patients transferred from a non-PCI capable hospital were treated within 120 minutes.³

After the STEMI app's implementation, we have been able to respond more quickly to STEMIs during lab hours and particularly well during the night, when

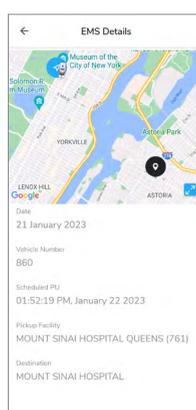
Multi-Patient Tracking



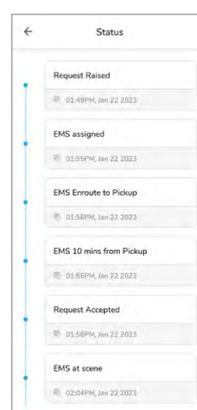
Communication



GPS Location



Status Updates



Medications and More



James Supp

Diagnosis: Aortic valve disease

Treatment: Placement of TAVR device



“They solved a problem I didn’t know I had with expertise.”

bringing together the physicians, nurses, technicians, and transfer personnel is more difficult. There has been a reduction of the time the patient spends in the ED before transfer, as well as the all-encompassing 120 minute door-to-device metric which has allowed us for the first time to consistently meet the AHA registry’s goal of 75% of cases staying under 120 minutes.

For STEMI patients, time is myocardium. Faster treatment leads to better procedural outcomes and faster recovery with less permanent damage to the heart. After seeing the positive results of the Queens to Mount Sinai main campus pilot, the Health System leadership has approved the expansion of the STEMIcathAID application to include Mount Sinai Morningside and Mount Sinai West. We will continue to leverage technology and innovation to improve our patient outcomes.

“When my cardiologist told me I was having aortic valve issues, my initial reaction was shock. I’ve been getting echocardiograms since I was 70 and nothing had ever shown up on them—plus, I wasn’t experiencing any symptoms. I know people who have had valves replaced but I never thought I would be one of them. I left the cardiologist and got back to my apartment, and the phone was ringing when I was walking through the door. I was not expecting Dr. Sharma to call so soon, but he asked me to come in, even though I was a little unsure.

“After my initial consult, Dr. Sharma agreed to hold off my procedure for January because I wasn’t experiencing any major symptoms. On the day of the operation, Dr. Sharma, Dr. Kini, and the anesthesiologist did a wonderful job of making me feel comfortable and relaxed. Their attitude that day was very positive, which in turn, helped me stay positive. I have tremendous respect for the way Dr. Sharma and his team carried themselves. Once I had come out of surgery, they even made a point to call my brother in Connecticut to let him know everything had gone well which I really appreciated.

“The day after the operation, the electrophysiology department at Mount Sinai determined I needed a pacemaker as well, so the next day I went back into surgery. To my surprise, I had no pain after the surgeries or during my recovery, which I think comes down to the skill of the doctors and that means that the Mount Sinai doctors are very talented.

“I had an extraordinary experience. The news about needing a heart procedure came out of the blue, and I was so thankful that my cardiologist called Dr. Sharma and that Dr. Sharma called me. They solved a problem I didn’t know I had with expertise. I’ve had some great doctors over the years, and Dr. Sharma was one of the best.”

References

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2. Garcia H, Kini A, et. Al. Am Heart J. 2022; Nov; 253:30-38.
3. Jollis J, Jacobs A, et. Al. JAMA, 2022;328(20):2033-2040.

TAVRbot, Angio3D, and Other Apps

ANNAPOORNA S. KINI, MD, AND YULIYA VENGRENYUK

Structural heart procedures such as Transcatheter Aortic Valve Replacement (TAVR) and Transcatheter Edge-to-Edge Repair (TEER) pose challenges to both the patients undergoing them and the heart team working with them. There are a number of cardiologist appointments (general, surgical, interventional), echo, CT, and other visits that need to be scheduled and all considered together in the “heart team approach” we use at The Mount Sinai Hospital.

TAVRbot

TAVRbot, our custom-built patient platform, was designed to help the patients and doctors through the treatment journey. There is a system to provide the patient with information pertinent to the stage of their treatment. There is also a secure place to communicate with a chatbot trained to answer some of our most commonly-asked questions. Providers can interact directly with the patients for more specific or clinical questions. Finally, a dashboard helps our physicians quickly understand how far along in the treatment pathway their patients are.

The TAVRbot platform increases the available resources our patients have when going through challenging procedures.

The TAVRbot platform increases the available resources our patients have when going through some of our most challenging procedures. Through technology and coordinated care, we will continue to strive for the best patient experience and outcomes.

The composite image illustrates the TAVRbot ecosystem. On the left is a dashboard for Mount Sinai, featuring a sidebar with navigation options: Dashboard, Patient Management, SMS Management, Chat Bot, User Management, Referrals, and Surveys. The main content area shows two overview sections: 'TAVR Overview' and 'Mitral Clip Overview'. Each section contains five data points: Total No. of active patient, Total No. of patients added, Patients under procedure, Complete procedure till date, and Total unanswered questions. The TAVR Overview shows 8 active patients, 9 added, 0 under procedure, 1 complete, and 0 unanswered. The Mitral Clip Overview shows 4 active patients, 4 added, 0 under procedure, 2 complete, and 0 unanswered. In the center is a 'Heart Team' diagram, a red heart with six surrounding roles: Interventional Cardiologists, Cath Lab OR Staff, Echocardiographers, Valve Clinic Coordinator, Cardiothoracic Surgeons, and ICU. On the right is a screenshot of a patient chat interface with MSH. It shows a notification about hospital stay, a question 'What is Aortic Stenosis?', and an answer explaining the condition. Another question 'What is TAVR?' is shown below.

Robin Vitalis

Diagnosis: I Vessel CAD (LAD)

Treatment: Complex PCI and placement of 1 drug-eluting stent



“Dr. Kini saved my life twice—she gave me back my life.”

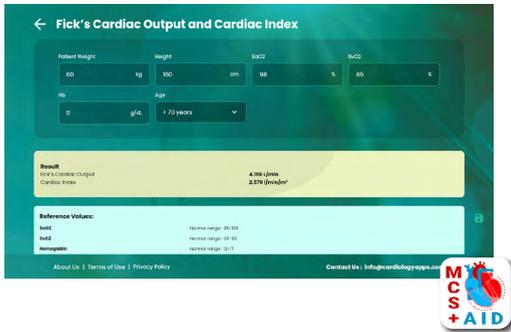
“I was diagnosed with stage 3 lung cancer in 2002, when my daughter was just six years old. The radiation treatment to target my lymph nodes in the bronchial area had impacted my heart, and I had heart problems for 20 years.

“In 2019, I was experiencing weakness and shortness of breath. I couldn’t walk 10 steps without being forced to sit down and rest. I was always tired. I know now it wasn’t a normal tired. I would take a shower and have to lie down. Turns out there was a 70% blockage in the main artery, and the doctors in my community on Long Island didn’t want to do the procedure. My husband, James, said, ‘We have to go to Mount Sinai immediately.’ That was where I met Dr. Kini. After a consultation with her we knew she was the right one to take on my case. She expertly placed a stent, and the experience was amazing. I felt great afterwards and continued to feel great for three years.

“And then in 2022, I started feeling that weakness again—you learn to listen to your heart, and I knew something was wrong. My husband and I immediately called Dr. Kini at Mount Sinai, and they got me in right away. Turns out there was a blockage right underneath the first blockage. Once again, she expertly placed a stent and got me back to myself again.

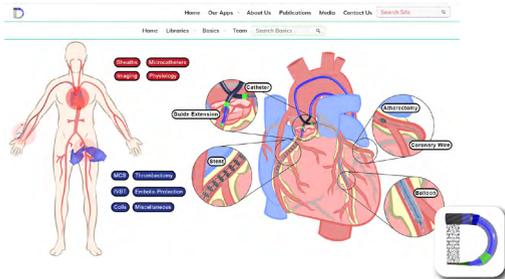
“I feel like a new person! I can do everything with my granddaughter, who is happy to have her Gaga back in full force. And I’m back to my healthy habits; I have a little gym in my basement and I walk every day.

“Dr. Kini saved my life twice—she gave me back my life. She had such an impact on my life I can’t put it into words. I wouldn’t go anywhere else but Mount Sinai.”



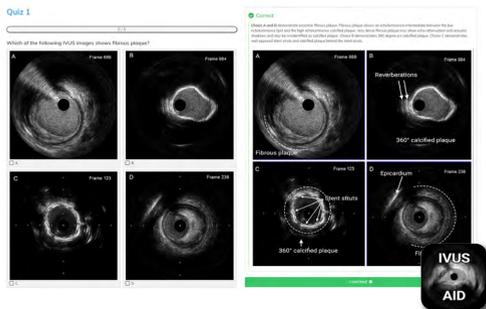
MESAID

Deciding mechanical cardiocirculatory support strategy requires a combined knowledge of the available devices, the patient’s clinical presentation, and calculation of key hemodynamic variables such as the cardiac output and pulmonary artery pulsatility index. MESAID was developed to help introduce trainees to the devices and basics of cardiogenic shock through text and an interactive algorithm including both cardiogenic shock and cardiac arrest. Additionally, a number of hemodynamic calculators help quickly calculate key variables used in the decision-making of device escalation and weaning algorithms.



DeviceAID

Every Catheterization Laboratory has its own toolbox of preferred devices in equipment storage, and nobody can be expected to remember the maximum expansion size of every stent, every possible combination of lengths and diameters of every balloon, or the exact crossing profile of every microcatheter. DeviceAID was created to outline the many categories of devices used in common interventional cases, as well as provide a vast library of many hundreds of devices that you can search and filter based on key specifications.



IVUSAID

This application will follow in the footsteps of our second-released and second-most downloaded imaging application OCTAID. IVUSAID will teach the key concepts of intravascular ultrasound imaging through a large curated collection of carefully described and annotated images and pullback videos. With a detailed basics section, more than 20 case reviews, image interpretation, and 50 quiz questions, the application will help improve imaging competence. This is particularly important for interventional fellows in a time when the use of imaging is on the rise in the U.S.

References

1. Rate of Peri-Procedural Stroke Observed With Cerebral Embolic Protection During Transcatheter Aortic Valve Replacement: A Patient-Level Propensity-Matched Analysis. *Eur Heart J* 2019;40:1334.

Elliot Zeisel, PhD, PC

Diagnosis: III Vessel CAD (RCA, LAD, LCx)

Treatment: Complex PCI, rotational atherectomy and placement of 2 stents



“That’s what I feel like Dr. Sharma and his team did—they rebuilt my heart.”

“In the summer of 2020, I ended up at Mount Sinai for eight days recovering from COVID-19. I continued to live with the resulting fatigue. About a year later, in the summer of 2021, I was on a walk near my home with my wife, and started feeling short of breath. Luckily, my primary care physician’s office was nearby, and she brought me in immediately. She did a careful exam and suggested I see a cardiologist. On examination, he sent me for a stress test.

“The doctor performing the stress test became concerned and sent me right to The Mount Sinai Hospital. I met with Dr. Sharma, and we agreed to get me in first thing the next day. Dr. Sharma’s team had me prepped, I was on the table, mildly sedated. He showed me on the screen that my LAD was completely blocked—I knew this artery is what they call the “widowmaker.” I also had two other arteries occluded—the RCA and LCx. Dr. Sharma said we can either fix the most troublesome one today and you can have the others done in five weeks, or come back in a few weeks and we’ll do all three.

“So I said ‘You’re here, I’m here, I can see what we’re looking at and it doesn’t look good, let’s go for it.’ Over four hours, he placed two stents in the LAD and got it open. I went home to recover, happy to have avoided a heart attack. Dr. Sharma and his whole staff were thoughtful, reassuring, and kind. I came back five weeks later so they could work on the remaining arteries. He put in another stent, and this time it was a breeze.

“I come from a family in New York who were in the machine tool rebuilding business. We would fix the gears, rewire, repaint, and send them out for another 50 years of service. That’s what I feel like Dr. Sharma and his team did—they rebuilt my heart.”

Safety and Indication of Transcatheter Edge-to-Edge Repair (TEER) Using MitraClip and PASCAL Devices

ANNAPOORNA S. KINI, MD, AND PARASURAM MELARCODE KRISHNAMOORTHY, MD

Valvular heart disease remains an important public health problem, imposing a huge economic burden on health care systems in the United States. Moderate or severe valvular disease is common, impacting 12 percent of the general population, with the prevalence increasing with advancing age. Among all valvular heart diseases, mitral regurgitation (MR) is the most common valvular abnormality, affecting 10 percent of individuals aged >75 years. Mitral regurgitation can be classified into primary or secondary functional MR. Structural abnormalities of mitral valve lead to primary MR. Mitral regurgitation due to primary pathology in the left ventricle is called secondary or functional MR.

When a mitral valve is determined to have a severe backflow of blood across the valve, the patient's cardiologist will refer them to a structural heart program, where they will have a consult with the structural heart team and several noninvasive studies to determine

procedure eligibility and plan for the procedure. Candidacy for the MitraClip™ procedure is determined by multidisciplinary heart team evaluation and based on a number of factors and tests performed at Mount Sinai. The tests required are transthoracic echocardiogram (TTE), transesophageal echocardiogram (TEE), and consults with an interventional cardiologist, a cardiothoracic surgeon, and heart failure specialist. Surgical repair would typically restore the mitral valve function and minimize the mitral regurgitation. Transcatheter edge-to-edge repair (TEER) by MitraClip is currently indicated in patients with primary MR who are high risk for mitral valve surgery, and asymptomatic patients with secondary MR despite optimal guideline directed medical therapy (GDMT). TEER for primary MR remains the second line therapy for those deemed too high risk for MV surgery as it does not

Candidacy for the MitraClip procedure is determined by multi-disciplinary heart team evaluation and based on a number of factors and tests performed at Mount Sinai.

completely eliminate the MR but rather reduces it. The MitraClip device is a small metal alloy clip covered with a polyester fabric that is implanted on the mitral valve. The MitraClip works by bringing the two leaflets of mitral valve together, which allows the valve to close more effectively and reduce the amount of blood that flows backwards. With TEE and the patient under general anesthesia, the device is implanted using a catheter inserted through the leg vein to the heart. The MitraClip procedure takes about two hours. Usually one to two clips are implanted in the mitral valve during the procedure, until a favorable result is obtained. MitraClip is an extremely safe procedure, but there is very small (<1 percent) risk of death, stroke, heart attack, bleeding, vascular injury, clip detachment, and infection. Usually two to three days of hospital stay is required. Patients should begin to feel relief of their

COAPT TRIAL
ANNUALIZED HF HOSPITALIZATION
THROUGH THREE-YEAR FOLLOW-UP

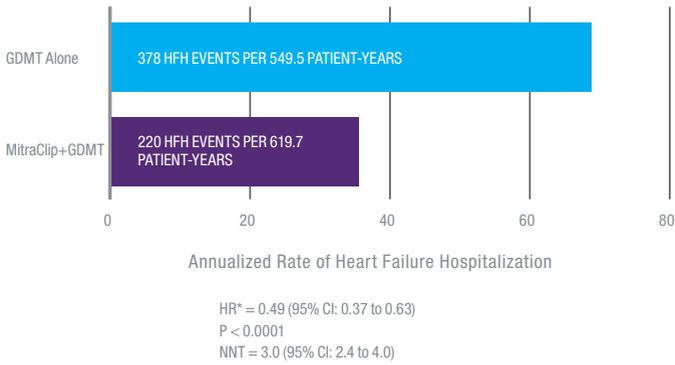


FIGURE 1: TEER WITH MITRACLIP PROCEDURES AT MSH 2018-2022

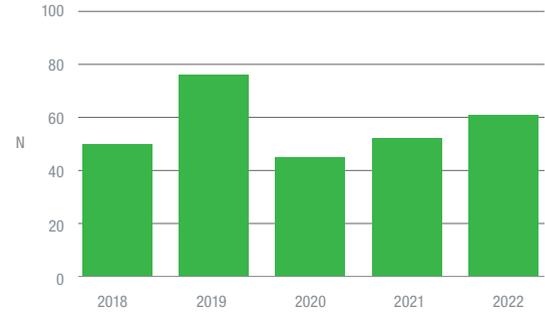
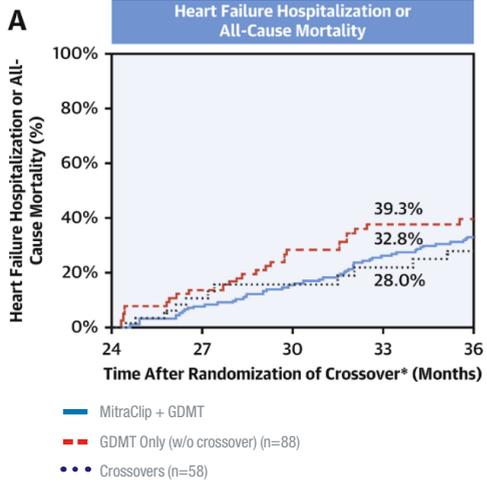


FIGURE 2

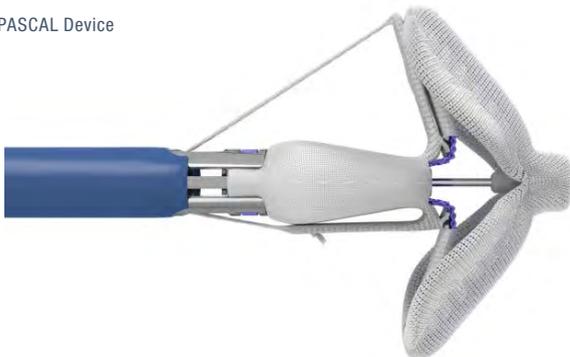
**Site Specific Metrics – Averages Over the Past 6 Months
MSH vs National Data**

Average MR Reduction		Average MR Post Procedure	
2.9	2.7	1.1	1.3
MSH	Nation	MSH	Nation
Average Gradient Post Procedure		Average Device Time	
2.6	3.3	25 mins	55 mins
MSH	Nation	MSH	Nation
30-day/1-Yr Mortality			
0/5%		2.9/16.6%	
MSH		Nation	

COAPT TRIAL



PASCAL Device



symptoms within a few weeks after their procedure. MitraClip™, in addition to the current medical therapy, will help improve the management of patients with heart failure. In the COAPT trial, MitraClip has been shown to improve the survival of patients with heart failure with reduced fraction (HFrEF) and reduce their hospitalization due to heart failure. Also GDMT patients who received MitraClip after completion of the trial had similar outcomes as of the original MitraClip patients.

The Mount Sinai Hospital experience with the MitraClip TEER procedure from 01/2018 to 12/2022 is shown in the figure 1 along with a less than 1 percent complication rate. Strict adherence to our highly effective and cautious protocol, appropriately complemented by post-procedure management, has helped us in optimizing our outcomes. Figure 2 shows site-specific metrics at MSH and in comparison to the national metrics. We are also planning to implement the Edwards Lifesciences PASCAL Precision Transcatheter Mitral Valve Repair System for appropriate patients which was recently approved by the FDA.

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William Haagenon

Diagnosis: Severe mitral valve disease

Treatment: Mitral valve transcatheter edge-to-edge replacement (TEER) with MitraClip device



“Dr. Sharma and his team had amazing attention to detail, and I felt in very good hands.”

“When I started experiencing shortness of breath and overall general difficulty doing normal tasks, I knew something wasn’t right. After visiting my primary care doctor and being referred to a cardiologist, I was told that I had mitral valve regurgitation. At first, we decided to take a ‘wait and see’ approach, and would check in with the cardiologist regularly to monitor the progress.

“Unfortunately, my mitral valve got worse, as did my symptoms. I could barely make it up the stairs. Finally, my cardiologist determined it was time to intervene. He called Dr. Sharma and asked if I might be a candidate for a MitraClip procedure, which is a way to repair my malfunctioning mitral valve without an open surgery.

“After preliminary testing, Dr. Sharma concluded that I was a good candidate for the procedure, and we scheduled my intervention. On the day of the procedure, they ran so many tests—I felt like they really cared. From beginning to follow-up, for the entire process, Dr. Sharma and his team carried themselves very professionally. I got to speak to Dr. Sharma both before and after my procedure and he was very comforting.

“I was able to go home just three days after my procedure, and noticed a difference right away. In a matter of a few more days, I continually felt better and the shortness of breath was gone. I was surprised at how quickly I felt better. Now, I’m able to do normal tasks more easily again. Dr. Sharma and his team had amazing attention to detail, and I felt in very good hands.”

Innovations in Transcatheter Mitral Valve and Tricuspid Valve Interventions

GILBERT TANG, MD, PARASURAM MELARCODE KRISHNAMOORTHY, MD, AND STAMATIOS LERAKIS, MD

Transcatheter mitral valve interventions have evolved significantly, with >150,000 transcatheter edge-to-edge repair (TEER) procedures using the MitraClip™ G4 (Abbott Structural Heart) device having been performed for primary and secondary mitral regurgitation (MR) for the past 15 years, and the PASCAL Precision (Edwards Lifesciences) device recently approved by the FDA to treat primary mitral regurgitation in the United States. TEER with the MitraClip G4 system is now a mature procedure and Mount Sinai has one of the most efficient procedural performances in the New York area. In patients not eligible for TEER, transcatheter mitral valve replacement (TMVR) is an emerging alternative if anatomically suitable. TMVR in failed prosthetic valve and rings (mitral valve-in-valve, valve-in-ring) with the balloon-expandable SAPIEN 3 valve is FDA

approved, but TMVR in native mitral disease remains under clinical investigation. Mount Sinai is one of the leading sites for the Medtronic APOLLO pivotal trial with the Intrepid valve using a transfemoral approach without surgery. Other devices in clinical trials include the Abbott Tendyne and Cephea, and Edwards SAPIEN M3 and Eos.

Transcatheter tricuspid valve interventions have progressed rapidly over the past year to treat symptomatic severe tricuspid regurgitation. The Abbott TriClip system has completed the TRILUMINATE early feasibility study with sustained favorable 1-year outcomes in TR reduction, right ventricular remodeling and improvement in quality of life. The TRILUMINATE pivotal trial, which randomizes patients to optimal medical therapy versus TriClip G4 system repair, has completed enrollment with data to be presented in 2023, and Mount

Transcatheter tricuspid valve interventions have progressed rapidly over the past year to treat symptomatic severe tricuspid regurgitation (TR)

Sinai is one of the leading sites in the New York area. The Edwards PASCAL tricuspid repair system has begun its pivotal trial as well.

Three-dimensional intracardiac echo (ICE) may improve the ability to image the tricuspid valve during the procedure to improve therapy expansion, and Mount Sinai is one of the leading sites in the country to use 3D ICE in conjunction with transesophageal echo (TEE) to guide transcatheter tricuspid interventions. Transcatheter tricuspid valve replacement for native disease has seen growing clinical experience with the Medtronic Intrepid and Edwards Evoque devices showing favorable 30-day and 6-month outcomes, but high pacemaker rates and bleeding issues, as well as need for anticoagulation and unknown risk of valve thrombosis, will make this more a complementary therapy to transcatheter tricuspid repair, in patients who are not anatomically suitable for repair.

Alan Sclar

Diagnosis: 1 Vessel CAD

Treatment: Atherectomy and placement of stent in left anterior descending artery



“I have to say, I feel like a different person.”

“Though I was generally in good health, as I reached my 50s, my cardiologist started doing annual tests to make sure my heart was healthy. A few years ago, at one of these visits, my calcium score came back higher than it had ever been before. He said, ‘Out of an abundance of caution, I’d like to have you go for an angiogram.’ He sent me to Dr. Sharma and I remember meeting him for the first time. He was at once humble and very confident and that made me feel at ease right away. I knew I was in good hands.

“I remember waking up from the procedure and he had a smile on his face. He explained that when they looked at the arteries of my heart, everything was mostly normal, but my left anterior descending artery, what people sometimes call the ‘widowmaker’ artery, was 98% blocked. He placed a stent, cleared the blockage and I haven’t had any issues since.

“Up until the time that I had my procedure, I weighed around 300 pounds, but I never thought I had a lack of energy. But after the procedure, I had a new level of energy. I decided that I was given this second chance and I started reading about living a healthier lifestyle. I adopted a vegan diet and now I work out and lift weights and I have to say, I feel like a different person. I now have a lot of energy and vigor, and I even feel sharper mentally. I feel like I can contribute even more than I could before. As the CEO of a startup and a single father, I need the energy.

“I always say life is too important to be taken seriously, but it’s so important to find the right people in your life. I feel so lucky Dr. Sharma has come into my life. He is the very best, he really saved me.”

View a video of Alan’s experience by scanning the code below

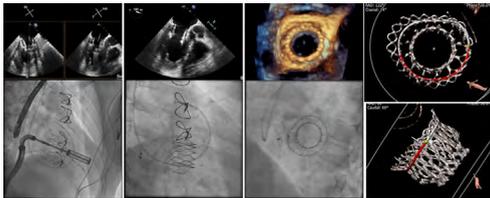


Figure 1: A Medtronic Intrepid valve being deployed under TEE and fluoroscopic guidance during transcatheter mitral valve replacement, and post-CT showing a fully circular inner valve.

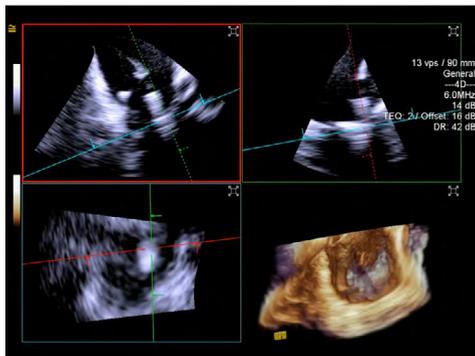


Figure 2: 3D ICE with real-time multiview reconstructions showing a TriClip device grasping the anterior and septal leaflets.

Left Atrial Appendage Occlusion (LAAO)

SAHIL KHERA, MD

Atrial fibrillation affects millions of adults and is associated with five-fold increased risk of ischemic stroke and arterial embolism. Stroke is also the fifth leading cause of death in the United States, and one-in four strokes in the U.S. are attributed to atrial fibrillation. These clots tend to preferentially form in the small outpouching within the left atrium called the left atrial appendage. This heightened risk of cardioembolic stroke in patients with atrial fibrillation is mitigated by use of systemic anticoagulation. Systemic oral anticoagulation (warfarin, apixaban, rivaroxaban, edoxaban, dabigatran) is the mainstay pharmacotherapy for stroke prevention in patients with atrial fibrillation. Unfortunately, some patients cannot tolerate oral anticoagulation due to a myriad of factors—patient comorbidities or systemic barriers. Chronic anticoagulation therapy is also associated with significant bleeding (especially in elderly patients, patients with uncontrolled hypertension, abnormal kidney/liver function, alcohol abuse etc.). Bleeding episodes can lead to

interrupted anticoagulation or a complete contraindication to oral anticoagulation therapy. These issues have led to development of non-pharmacological therapies for stroke prevention in carefully selected patients with chronic atrial fibrillation.

Left Atrial Appendage Occlusion (LAAO) is an established stroke prevention strategy in these patients. There are two commercially available LAAO devices—Watchman FLX (Boston Scientific, MN) and Amulet Device (Abbott, IL). (Figure 1) Since its Food and Drug Administration (FDA) approval in the United States in March 2015, more than 100,000 patients have undergone LAAO with the Watchman device. In addition, the FDA approved the Amulet LAAO device in August of 2021 and both the devices have demonstrated excellent safety and efficacy outcomes in trials and registry data. (Figure 2) The Watchman FLX is a single lobe occluder system and the Amulet is a self-expanding disk-lobe device. Despite the differences in device design; standard practice involves a minimally invasive femoral venous

This heightened risk of cardioembolic stroke in patients with atrial fibrillation is mitigated by use of systemic anti-coagulation.

procedure under general anesthesia using transesophageal guidance for device sizing, transseptal puncture, and assessment of final implant stability. Procedure time is 30–45 minutes and patients are discharged the next day and undergo a repeat echocardiogram at 45 days post procedure for assessment of per-device leaks. Anticoagulation can be stopped immediately after the device placement. Patients are maintained on 3–6 months of antiplatelet therapy (depending on bleeding risk profile) for complete device endothelialization to occur.

Our robust and extremely high volume structural heart program is one of the few interventional cardiology sites in the nation that offer the Amulet LAAO device. (Figure 3) Left atrial appendage occlusion using the devices can be considered for patients who have a contraindication for oral anticoagulation, have had a prior bleeding event, are at high risk of falls, have uncontrolled or poorly controlled hypertension, at-risk of drug-drug interactions, or poor adherence to life-long anticoagulation.

Parviz Edalat, DDS

Diagnosis: Congestive heart failure and mitral valve disease

Treatment: TEER using MitraClip™ Device



“Only three days after the procedure, I was discharged from the hospital and back to work.”

“Two years ago, I began experiencing shortness of breath, I was lethargic, and I couldn’t walk or move very fast without chest pain and tightness. When I began having these symptoms, I was surprised; I had always been healthy, I was watching my diet, and would take 40 minute walks three or four days a week. That was until my first symptom occurred on one of my walks. I noticed I was having shortness of breath more than usual, and it began to reoccur frequently. I made an appointment with my primary care doctor, who gave me an inhaler to try using on my walks or during the day whenever else I felt shortness of breath. But even with the inhaler, nothing felt any better. I decided to see a cardiologist who ran several tests and scans. The conclusion he came to was that I was in heart failure. To help alleviate some of my discomfort he put me on a couple of medications. But, just like the inhaler, they did nothing to ease my symptoms.

“Feeling defeated, I decided to switch my primary care provider. After telling my new doctor about my symptoms, and what the other doctors had done to try to help, I was referred to Mount Sinai. Dr. Sharma was assigned to my case and reconfirmed that I was in fact in heart failure. He told me it had progressed to where my only option was to do a MitraClip procedure. I was a little scared but because I believed in Dr. Sharma and his optimism, I decided to move forward.

“Only three days after the procedure, I was discharged from the hospital and back to work. I was glad to be able to go back to work because I have been a dentist for coming up on 50 years, it is a career I am passionate about and own my own practice in Manhattan near Central Park. I only work two days a week, but thanks to Dr. Sharma I am able to without discomfort or pain and am back to walking 30-40 minutes three or four days a week.”

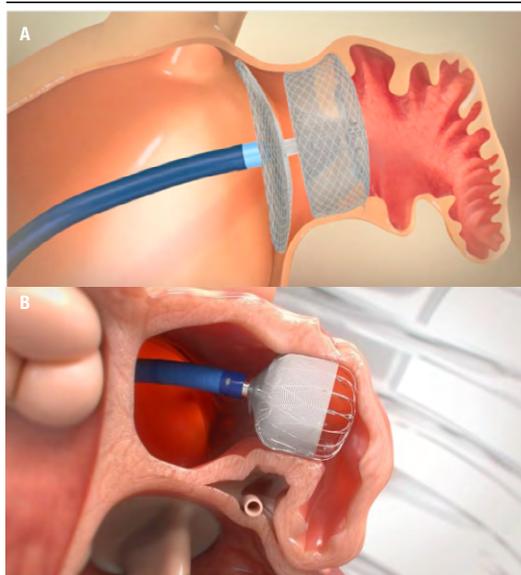


Figure 1: A) Abbott Amulet Left Atrial Occlusion device and B) Boston Scientific Watchman FLX device

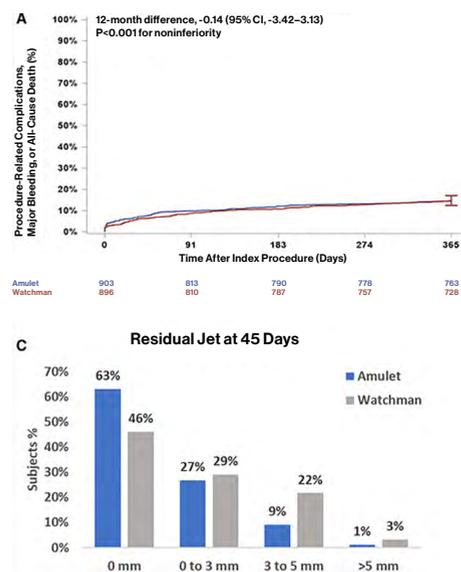


Figure 2: Data from Amulet IDE trial demonstrating excellent safety (A) and distribution of residual jets at 45 days (C)

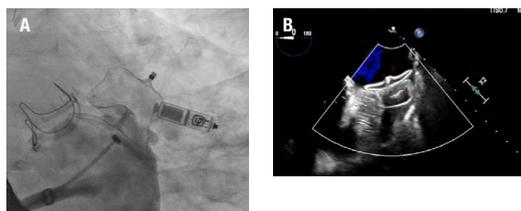


Figure 3: A) Abbott Amulet Left Atrial Occlusion device implantation and B) Complete occlusion of the left atrial appendage on imaging at 45 days.

Management of Critical Limb Ischemia Update

PRAKASH KRISHNAN, MD

Chronic limb ischemia (CLI) is the most severe form of peripheral arterial disease and is characterized by lower extremity rest pain, ulceration, and—in its most severe form—gangrene. CLI prevalence in the United States is estimated to be approximately two million. The most devastating outcomes for CLI patients are amputation and mortality, which are linked. Various meta-analyses suggest that amputation rates exceed 10% at one year and that factors associated with higher amputation rates include Black or Native American race, low income, Medicaid, and disease severity characterized by the Rutherford classification and presence of comorbidities (diabetics with CLI have a 50% higher probability of amputation versus those without diabetes). Amputation is associated with poor survival outcomes; however, the long-term prognosis for CLI patients is also generally poor. Using various data sources and methods, researchers have quantified that one-year mortality ranges from 15% to 40%, depending on risk factors.

For example, increasing disease severity (Rutherford 5 [ulcer] or Rutherford 6 [gangrene]) and diabetes are clearly linked to higher mortality in numerous studies. To put cardiovascular pathologies in perspective, Hosseiny et al (2016) have shown that in an era with primary PCI as the gold standard for ST elevation myocardial infarction (STEMI), the mortality rate is 7.3% at one year and 2.05% per year thereafter. Thus, early referral for endovascular or surgical treatment is crucial to prevent amputation and mortality in CLI patients.

Surgical vs. Endovascular Treatment

The most recent evidence suggests that there is a role for both surgery and endovascular treatment for CLI patients. The data from BEST-CLI, the largest head-to-head comparison of endovascular therapy and surgery in patients eligible for either treatment, shows level 1 evidence that in those who have an adequate single segment of great saphenous vein (SSGSV)

The most recent evidence suggests that there is a role for both surgery and endovascular treatment for CLI patients.

that could be used for bypass surgery, there was a statistically lower incidence of the primary outcome of all-cause death at 2.7 years than an endovascular-first approach in a similar population. In those without SSGSV conduits, primarily PTFE grafts were used for bypasses, showing no significant difference in relation to the primary outcome compared to endovascular techniques. It should be noted that some of the latest and most effective tools in endovascular therapy were used sparsely, such as drug-coated balloons in routine SFA interventions (< 10% use in SFA interventions). Unfortunately, a large proportion of CLI patients are either not good surgical candidates or refuse the risk of a larger open vascular operation. Lin et al (2019) showed that an endovascular-first treatment option is associated with improved amputation-free survival in select patients with CLI. They used California nonfederal hospital data to retrospectively look at patients with CLI undergoing revascularization from 2005 to 2013 and compared

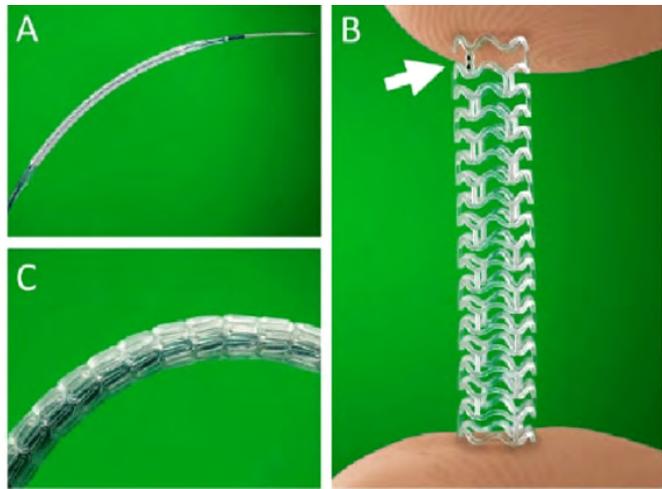
SAVAL™ DES BTK Stent



- Nitinol Self-Expanding Stent
 - Flexible crush resistant scaffold
 - Diameter compliant
- PTx drug coating (PBMA/PVDF)



Differentiated technology has been selected for Expedited Access Pathway (EAP) designation by FDA



(A) The Absorb Bioresorbable Vascular Scaffold is a balloon-mounted polymer structure. (B) There are dual radiopaque platinum markers (arrow) at either end to assist with fluoroscopic visibility as it is otherwise radiolucent. (C) It is made from a poly-L-lactide semicrystalline polymer backbone and a poly(D,L-lactide) polymer coating that contains the antiproliferative drug everolimus. Images provided by Abbott Vascular and used with permission.

amputation-free survival and time to reintervention for open versus endovascular treatment. Patients in the endovascular group were more likely to have renal failure, coronary artery disease, congestive heart failure, and diabetes. Open surgery was associated with a worse amputation-free survival rate with no difference in mortality compared to an endovascular-first approach in this population. We believe that with the latest endovascular techniques, there is a massive role for an endovascular-first approach for CLI, especially in patients who cannot tolerate surgery.

Up-and-Coming Treatments for CLI Endovascular Interventions

The armamentarium for treating below-the-knee (BTK) disease in CLI patients is vast and rapidly expanding. Currently, the standard of care for patients battling CLI is balloon angioplasty, which relies on a small balloon delivered via a catheter to the blockage to compress it against the arterial wall, opening the vessel, and restoring blood flow.

CUMULATIVE INCIDENCE OF ALL CAUSE AND CARDIOVASCULAR MORTALITY RATE DURING FOLLOW-UP BASED ON THE KAPLAN-MEYER SURVIVAL ANALYSIS

	Total mortality (SE)	Cardiovascular mortality (SE)
7 days	3.4% (0.005)	3.4% (0.005)
30 days	4.3% (0.006)	4.2% (0.006)
1 year	7.3% (0.007)	5.6% (0.006)
2 years	8.9% (0.008)	6.4% (0.007)
3 years	11.5% (0.009)	7.1% (0.007)
4 years	13.1% (0.01)	7.4% (0.008)
5 years	15.5% (0.012)	8.6% (0.009)

PUBLICATION	COUNTRY REGION	DATA SOURCE (YEARS)	POPULATION DETAILS	METHODS	LONG-TERM MORTALITY
Baser (2013) ¹⁹	United States	100% Medicare inpatient/outpatient denominator files (2007-2008)	US Medicare population	ICD-9 and CPI codes used to identify CLI cases	1-Year After CLI dx: 30.3% After CLI dx + amp: 40.4%
Soga (2014) ⁷⁷	Japan	Prospective, multicenter (n=17) database (2004-2011)	CLI patients undergoing endovascular treatment	Retrospective analysis of medical records	2-Year 41%
Abu Dabrh (2015) ³	Multi-national	Published literature (1986-2013)	Natural history CLI patients not receiving revascularization	Meta-analysis of 8 RCTs and 5 case series	1-Year 18%-22% ^b
Howard (2015) ⁷⁵	United Kingdom (Oxfordshire)	Medical records (2002-2012)	CLI patients within the OXVASC study population (no age restriction)	Prospective, population-based study	30-Day 7.4% 5-Year 29.2%
Reinecke (2015) ²⁶	Germany	German health insurer data (2009-2011)	Hospitalized CLI patients	ICD-10 diagnosis and German procedure OPS codes to identify cases and procedures	1-Year Rutherford 6: 34.2% 4-Year Rutherford 4: 37.7% Rutherford 5: 52.2% Rutherford 6: 63.5%
Luders (2016) ²⁴	Germany	German health insurer data (2009-2012)	Hospitalized CLI patients (Rutherford 1-3 as a reference group)	ICD-10 diagnosis and German procedure OPS codes to identify cases and procedures	Hazard Ratio vs Rutherford 1-3 median follow-up = years Rutherford 4: 2.01 Rutherford 5: 2.46 Rutherford 6: 3.59
Spreen (2016) ²⁷	The Netherlands	Pooled patient-level data from the PADI and JUVENTAS trials (2006-unknown)	CLI patients undergoing one of the PADI or Juventas interventions	Analysis of pooled RCT data	Time Point: Mort. (DM-/DM+) 6 months: 8.0%/12/8% 1 year: 17.9%/19.2% 2 years: 25.6%/32.0% 3 years: 31.3%/38.1% 4 years: 36.1%/43.0% 5 years: 48.0%/55.7%

This is used in conjunction with atherectomy, which aids in ablating the fibrotic tissue and calcium. Severe calcium can also be treated with intravascular lithotripsy or the Shockwave Lithoplasty® System, which has been shown to be safe and effective in the DISRUPT BTK trial. However, blockages treated only with balloon angioplasty have high rates of elastic recoil and restenosis. We believe that the ideal treatment for BTK CLI patients is drug delivery with a scaffold without leaving any metal behind so that future surgical access for a

bypass is not prohibited. Coronary drug-eluting stents (DES) have been evaluated for short infrapopliteal (IP) lesions in prior randomized control trials, showing superior patency rates and lower target lesion revascularization rates compared to balloon angioplasty. However, there were no significant differences in clinical improvement or amputation-free survival. Notably, no coronary DES are specifically labeled for IP use in the United States, and they are currently used for focal segments and as a bailout strategy. Two

up-and-coming technologies on the horizon in treating CLI patients are the SAVAL DES and the bioresorbable scaffold.

The SAVAL trial is testing the Saval™ DES (Boston Scientific Corporation) for the treatment of IP lesions and is a multicenter, randomized trial comparing DES to balloon angioplasty in 301 patients with CLI. The primary efficacy endpoint is 6-month primary patency.



Gary Heesemann

Diagnosis: Severe inoperable lower extremity vascular disease

Treatment: Endovascular reconstruction of occluded femoral and popliteal arteries



“Two of my children are getting married this year and I’m thankful I get to walk them down the aisle.”

“I worked for Con Edison Emergency Response and was a first responder for 30 years. After the 9/11 attacks I spent time working at Ground Zero—and I’ve had medical issues since then. I had been experiencing chronic pain since 2002 and no one could fix it.

“My medical issues were getting progressively worse. I was walking less and less because it would take me so long to recuperate just from walking. My calves would become rock hard and felt like there was no blood flow in my legs. I had numerous surgeries, bypasses, and angiograms to try and correct the issues. One of my surgeries had failed after only 31 days. In total, I had five surgeries and six procedures. I almost lost my leg because I got a staph infection after one of the surgeries. I had to retire at 64 because I just couldn’t walk anymore, it hurt too much.

“Frustrated with my lack of progress, I sought out a new doctor, who referred me to Mount Sinai. I went in on a Tuesday to have a few tests run and come Wednesday, the very next day, I was having a procedure. Dr. Krishnan and his team explained everything well to me and made sure I knew exactly what was going on. I also really liked the fellows he had on his team. Even though I had to stay in the hospital for a few days, I really did notice a difference right away. And that was 163 days ago, after 20 years of suffering.

“Now I’m walking every day, I no longer have difficulty getting around the grocery store. Two of my three children are getting married this year, and I’m thankful I get to walk them down the aisle because before my operation I wouldn’t have been able to.”

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Renal Artery Denervation for Refractory Hypertension

GEORGE DANGAS, MD, PHD

High blood pressure is one of the most common modifiable risk factors contributing to cardiovascular morbidity and mortality across the globe. Appropriate and durable blood pressure control results in lower incidence of cardiovascular events and prolonged life expectancy. Approximately 10% of patients with diagnosed hypertension have resistant hypertension, defined as a systolic blood pressure of 140 mm Hg or higher despite adherence to at least three maximally tolerated doses of antihypertensive medications. Patients with refractory hypertension remain at high risk of adverse cardiovascular events despite receiving appropriate medical therapy.

Over the last few years, catheter-based radiofrequency renal artery denervation (RAD) has emerged as a promising treatment option for patients with refractory hypertension. The sympathetic nervous system, in particular the neural cross-talk between the kidneys and the brain, play an important role in resistant hypertension. Experimental and clinical data has shown that denervation of

the renal sympathetic system reduces both renal and central sympathetic activity, as well as blood pressure, in patients with resistant hypertension. In addition, modulation of sympathetic activity might also reduce heart rhythm disturbances such as atrial fibrillation and ventricular arrhythmias.¹

In the SIMPLICITY-HTN-3 trial, 535 patients with refractory hypertension were randomly assigned to receive RAD with the Symplicity system (Medtronic, Santa Rosa, CA, USA) or a sham control procedure. At 36 months, RAD resulted in larger reduction in office systolic blood pressure compared with control (adjusted treatment difference -22.1 mm Hg [95% CI -27.2 to -17.0]; $p < 0.0001$) and 24 h ambulatory systolic blood pressure (adjusted treatment difference -16.5 mm Hg [95% CI -20.5 to -12.5]; $p < 0.0001$).² In addition, patients who received RAD spent longer time in therapeutic blood pressure range (i.e., better blood pressure control) than patients in the sham control group.² The procedure of RAD did not reveal any safety signals, both at short and long-

Over the last few years, catheter-based radiofrequency renal artery denervation (RAD) has emerged as a promising treatment option for patients with refractory hypertension.

term follow-up.² Similar findings were also shown in the SPYRAL HTN-ON MED trial.³

In conclusion, RAD appears to be a promising and effective treatment for high blood pressure resistant to maximally-tolerated medical therapy. Further iterations in device technologies as well as clinical evidence may establish RAD as a standard of care treatment for resistant hypertension.

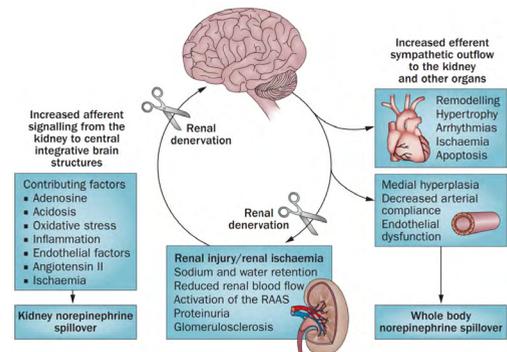


Figure 1: Pathophysiological effects of the sympathetic cross-talk between kidneys and brain.

Anne Schneider

Diagnosis: 1 Vessel CAD (LCx)

Treatment: Placement of 2 stents

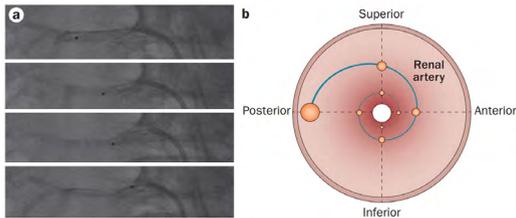


Figure 2: Renal artery denervation procedure. The electrode is positioned under fluoroscopic guidance (A). Radiofrequency energy is delivered while the catheter is simultaneously pulled back toward the ostium and rotated (B)¹.



“I haven’t had any complications in years and it’s all thanks to Dr. Dangas and his team.”

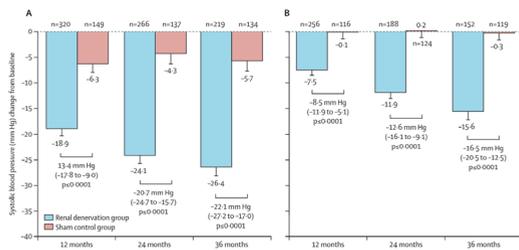


Figure 3: Long-term effect of renal artery denervation on blood pressure measurements in the SYMPLICITY-3 trial².

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“In 2003, I had a pacemaker implanted, and in 2013, I needed its battery replaced. I had it done on Valentine’s Day at Mount Sinai. A simple procedure, in and out the same day. But, over the next few days, I was extremely tired, became very bloated, and had almost no appetite. Four days later, walking across the street to my apartment, a gust of wind hit me full on and I could not catch my breath. I told my husband something was not right and he needed to get me to Mount Sinai, immediately. Within 20 minutes of arriving at the ER, I was triaged, in a bed, and having a heart attack.

“After taking my full medical history, I was told that I had probably been in heart failure for months. Looking back at those past four months, it made perfect sense. Just walking into the kitchen for breakfast would land me back in bed for a lengthy nap, one of several during my day.

“After being stabilized in the ER and being admitted to a cardiac bed it was explained that I would need two stents. They would treat the 99% blocked artery first and have me return in six weeks for a second artery that was only 60% blocked. Minutes after waking up from my first stent, I felt as if I had been to a spa for a week. Amazing what getting oxygen can do for you!

“My admitting doctor told me that Dr. George Dangas would be my surgeon and I met him just before surgery. I had no idea at the time how much I would come to rely on him. He is a great listener and diagnostician. His advice has always been direct, but never alarming. I value and admire his great skill as a surgeon and his caring attention, not only to me, but to my husband, who had TAVR surgery two years ago, performed by Dr. Dangas. We count on Dr. Dangas to be the captain of our extraordinary team at Mount Sinai, and he never disappoints. From the bottom of our hearts, thank you, Dr. Dangas and Mount Sinai.”

How to Measure Coronary Microvascular Dysfunction

JOSEPH SWEENEY, MD

Patients with chest pain and non-obstructive coronary artery disease (NOCAD) continue to be a diagnostic and therapeutic challenge in the Cardiac Catheterization Laboratory. Approximately 50% of patients undergoing invasive coronary angiography for typical angina have no significant coronary artery disease defined by coronary artery stenosis $\geq 50\%$.¹ Moreover, a substantial portion of these select patients (up to 60%) without obstructive CAD will have coronary microvascular dysfunction (CMD) and are at a higher risk of adverse clinical outcomes compared to the general population without CAD.²

The coronary microcirculation [Figure 1] contributes up to 50% of total coronary vascular resistance and through complex mechanisms contributes to the regulation of coronary blood flow and exchange of oxygen and metabolites to the myocardium during stress or demand. Dysfunction of this regulation can contribute to typical angina symptoms as well as other cardiovascular disease (INOCA, MINOCA, and HFpEF). Coronary

microvascular dysfunction has many pathological etiologies and is defined as increased resistance and/or impaired vasodilation of the microvascular bed. While noninvasive imaging modalities (PET, Cardiac MRI etc.) allow identification of impaired vasodilator capacity and quantification of microvascular function, it wasn't until the adaptation, validation, and availability of an invasive assessment of microvascular function, known as the Index of Microvascular Resistance (IMR), that has our ability to accurately assess and diagnosis these patients at the time of invasive coronary angiography truly advanced.

First described in 2003, IMR selectively measures microvascular function and is defined simply as the product of the distal coronary pressure (Pd) and mean transit time of a saline bolus during maximal adenosine induced hyperemia (TmnHyp). Through the use of a novel coronary wire capable of measuring proximal and distal coronary pressure and flow (PressureWire) and commercially

Patients with chest pain and non-obstructive coronary artery disease (NOCAD) continue to be a diagnostic and therapeutic challenge in the Cardiac Catheterization Laboratory.

available software through Abbott Vascular (Coroventis CoroFlow), the IMR can be accurately and quickly measured with minimal risk [Figure 2]. An abnormal IMR > 25 is associated with worse CVD outcomes and unlike other invasive measurements of microvascular function (Coronary Flow Reserve or CFR), is independent of epicardial function and highly reproducible and has quickly become the standard for this assessment.

While a comprehensive invasive functional assessment of coronary microcirculation entails the investigation of both vasodilator as well as provocative vasoconstrictor responses, the evaluation and measurement of microvascular resistance is frequently used at the Mount Sinai Cardiac Catheterization Laboratory as part of the work up for patients with chest pain without obstructive coronary artery disease aiding in diagnosing or excluding CMD and providing better therapeutic options.³

Maurice Hurt

Diagnosis: Acute MI, V-fib arrest

Treatment: Emergent PCI and full revascularization



“Dr. Sweeny had a comforting approach, I instantly felt I could trust him.”

“I work as a corrections officer on Rikers Island and one day last September I began feeling some pretty serious chest pains. Before long, I was in an ambulance to Mount Sinai Queens. While I was waiting to receive treatment at the clinic there, I had a heart attack. I woke up in Queens—they had to resuscitate me with the defibrillator. Then they sent me to Mount Sinai in Manhattan. That’s when I met Dr. Sweeny.

“I’m only 35, so I had a million thoughts in my mind, but when Dr. Sweeny came in, I was like ‘This guy is here to help.’ He simply said, ‘Don’t worry about it, this is something you can recover from.’ Dr. Sweeny had a comforting approach, I instantly felt I could trust him.

“Turns out, I had three blockages in three different arteries. He said the LAD was the main culprit and what had caused the heart attack. We fixed that first, and then over the next two months, he did all three in three separate procedures.

“After the first intervention, I started feeling better, but after the third in November, it was night and day. I feel normal, back to how I was prior to the incident. I used to get a lot of headaches and those have stopped. I’ve also lost a lot of weight from being able to move around. I feel clearer and lighter and like my lungs work.

“The experience was fantastic. Customer service is a huge thing for me, and theirs was second to none. Everyone was so friendly and helpful, if I needed anything they took care of it right away. It’s an easy process working with Mount Sinai. I live in Long Island, and I’d rather travel to Mount Sinai than deal with anyone else.

“Dr. Sweeny? I call him the legend—the greatest of all time—the GOAT.”

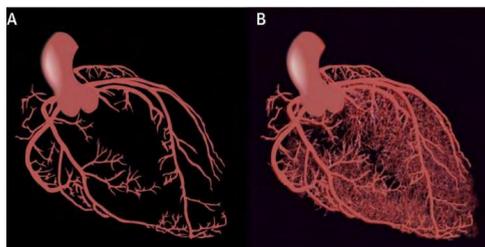


Figure 1: A. Epicardial coronary circulation. B. Epicardial and microvascular coronary circulation. [4]



Figure 2: Coroventis CoroFlow software interface

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Noninvasive and Invasive Detection of Vulnerable Plaque and Emerging Therapies

PEDRO MORENO, MD

The evolution from stable coronary disease to plaque rupture and thrombosis is mediated by three important mechanisms: 1) Expansion of the necrotic core; 2) Thinning of the fibrous cap; and 3) Increased macrophage infiltration (1). These deleterious processes may be stabilized by aggressive medical therapy. Intense LDL-Cholesterol reduction demonstrated improved clinical outcomes in primary and secondary prevention. Hence, precise characterization of these mechanisms of plaque stabilization is of vital relevance. High-resolution, multi-modality invasive imaging by Intravascular Ultrasound (IVUS), Optical coherence tomography (OCT), and Near Infrared Spectroscopy (NIRS) have evolved as the most relevant techniques.

The Cardiac Catheterization Imaging Center at Mount Sinai

Hospital led by Annapoorna Kini, MD, has completed over a decade of research evaluating the mechanisms of plaque stabilization with lipid lowering therapy in human coronary artery disease (CAD).

The first study characterized the effects of lipid therapy in the expansion of the necrotic core (2). The Yellow Trial randomized 87 patients with multivessel CAD undergoing coronary intervention and at least 1 other severely obstructive (FFR ≤ 0.8) non-target lesion (NTL) to intensive (Rosuvastatin 40 mg daily) or standard-of-care lipid-lowering therapy. NTLs were evaluated at baseline and after 7 weeks of therapy with FFR, NIRS and IVUS. The primary endpoint was reduction in the necrotic core evaluated as lipid core burden index (LCBI) as measured by NIRS. Results at follow-up showed

The Cardiac Catheterization Imaging Center at Mount Sinai Hospital led by Dr. Annapoorna Kini has completed over a decade of research evaluating the mechanisms of plaque stabilization with lipid lowering therapy in human coronary artery disease.

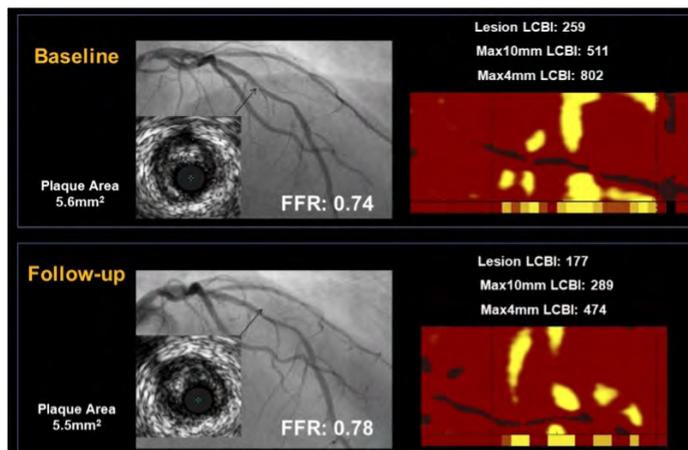
a significant LCBI reduction in the intensive versus standard group (149.1 [210.9 to 42.9] vs. 2.4 [36.1 to 44.7]; $p= 0.01$); (See Figure). Plaque morphology by IVUS and hemodynamic severity by FFR were not different between the two groups. In conclusion, intensive statin therapy will reduce the expansion of the necrotic core in obstructive coronary lesions.

The second Yellow Trial characterized the effects of lipid therapy on fibrous cap thickness and macrophage content (3). Following the same protocol, 85 patients were evaluated by OCT of an obstructive NTL. All subjects received 40 mg of rosuvastatin daily for 8 to 12 weeks, when the NTL lesion was re-imaged. Baseline OCT minimal fibrous cap thickness (FCT) was 100.9 ± 41.7 μ m, which increased to 108.6 ± 39.6 μ m at follow-up. Macrophage length was 9.8 ± 5.4 μ m, which decreased

to 8.8 ± 5.1 mm at follow-up. Furthermore, cholesterol efflux capacity was also improved at follow-up, and was associated with FCT. Finally, blood monocyte microarray analysis detected 117 genes that were differentially expressed at follow-up compared to baseline, including genes playing key roles in cholesterol synthesis (SQLE), regulation of fatty acids unsaturation (FADS1), cellular cholesterol uptake (LDLR), efflux (ABCA1 and ABCG1), and inflammation (DHCR24). In conclusion, intensive statin therapy will increase FCT and reduce macrophage infiltration in obstructive coronary lesions.

The third Yellow trial characterized the effects of the PCSK9 protein inhibitor evolucumab on fibrous cap thickness and lipid content as measured by OCT and NIRS respectively (4). In addition, blood samples were drawn during baseline and follow-up to assess the transcriptomic profile in blood monocytes by targeting 50M reads per cell using conventional bulk RNA sequencing. Results of this trial were presented at the American College of Cardiology Scientific Sessions as a late breaking clinical trial in New Orleans, March 2023.

In conclusion, multimodality intracoronary imaging can clearly identify and quantify the most relevant mechanisms associated with plaque stabilization, leading to reduction of coronary events.



Baseline: Multi-imaging evaluation before starting high-dose statin. Coronary angiogram showing a severely obstructive stenosis in the mid left anterior descending artery (arrow), cross-sectional intravascular ultrasound image with quantification of plaque area, fractional flow reserve consistent with flow limiting stenosis at 0.74 and Near Infrared Spectroscopy image showing a max4mm Lipid Core Burden Index of 802.

Follow-up: Multi-imaging evaluation at follow-up after high-dose statin. Coronary angiogram showing a no significant changes on the mid left anterior descending artery lesion (arrow), no significant changes on the plaque area evaluated by intravascular ultrasound, and no significant changes in the fractional flow reserve. Most importantly, Near Infrared Spectroscopy image shows a significant reduction in lipid content with a max4mm Lipid Core Burden Index of 474.

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Timing of Noncardiac Surgery Post Stenting

ROXANA MEHRAN, MD

Between 5–25% of patients undergoing coronary stenting require non-cardiac surgery within two years. Dual antiplatelet therapy (DAPT) with aspirin and a P2Y12 inhibitor is recommended after percutaneous coronary intervention (PCI) to prevent thrombotic complications, although at the cost of increased bleeding. As surgery is one the most common reasons for premature DAPT cessation due to bleeding concerns, postponing the procedure until the DAPT course has been completed is desirable. However, delaying surgery may not always be feasible, and the perioperative management of antiplatelet therapy poses a recurring dilemma in clinical practice which mandates careful weighing of the thrombotic and bleeding risks of each patient.¹

The time interval between PCI and surgery is arguably the most important determinant of thrombotic risk. There is an inverse

relationship between the risk of perioperative cardiovascular events and the timing of surgery after PCI (Figure 1). Allowing sufficient time for endothelial coverage of the newly implanted stent prior to interrupting DAPT and proceeding to surgery is critical to prevent thrombotic events. In recent years, new-generation drug-eluting stents with improved design and materials, including thinner struts and enhanced biocompatibility, have allowed abbreviating the minimum DAPT duration to as short as 1 month. In keeping with this, observational studies suggest that thrombotic risk is highest when surgery is performed within 4–6 weeks of stenting, and gradually attenuates over time.

When evaluating the optimal timing of surgery post-stenting, the first step is to determine the urgency of the procedure. In case of emergency or urgent surgery, this should be carried out without

According to the US guidelines, elective surgery is contraindicated within 3 months of drug-eluting stent implantation, can be considered after 3–6 months if the risk of delaying surgery is greater than the risk of stent thrombosis

unnecessary delay to save life or organ function, regardless of the ongoing antiplatelet therapy. A time-sensitive surgery should be performed as soon as possible as there is a time-dependent risk (e.g., cancer surgery) but allows sufficient time to manage perioperative DAPT (five to seven days) on the basis of individual bleeding and thrombotic risks. Meanwhile, elective surgeries should be postponed beyond the recommended standard DAPT course. According to the US guidelines, elective surgery is contraindicated within 3 months of drug-eluting stent implantation, can be considered after three to six months if the risk of delaying surgery is greater than the risk of stent thrombosis, and should ideally be performed >6 months post-stenting.² In 2022, the new European guidelines have been released and they make an important distinction on the timing of surgery based on the

clinical presentation leading to PCI (i.e., elective versus acute coronary syndrome). It is recommended to delay elective surgery that requires DAPT discontinuation until 6 months after elective PCI and until 12 months after an acute coronary syndrome. If surgery is time-sensitive, however, this can be performed after a minimum of one month of DAPT treatment post-elective PCI and three months after an acute coronary syndrome (Figure 2).³ If this is not possible, perioperative bridging of DAPT with intravenous antiplatelet agents, cangrelor or glycoprotein IIb/IIIa inhibitors, should be considered. In all circumstances, aspirin should be continued if the bleeding risk allows.

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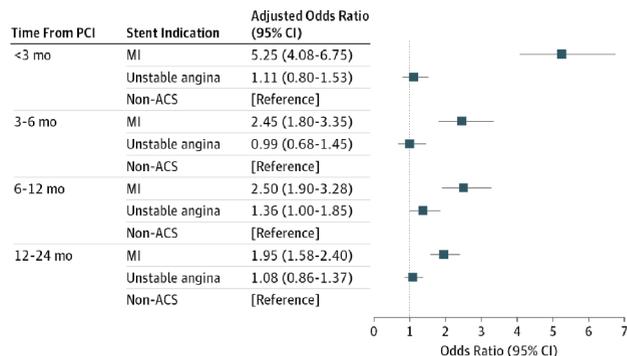


Figure 1: Risk of major adverse cardiac events by stent indication and time from PCI. From Holcomb CN et al. *JAMA Surg.* 2016 May 1;151(5):462-9.

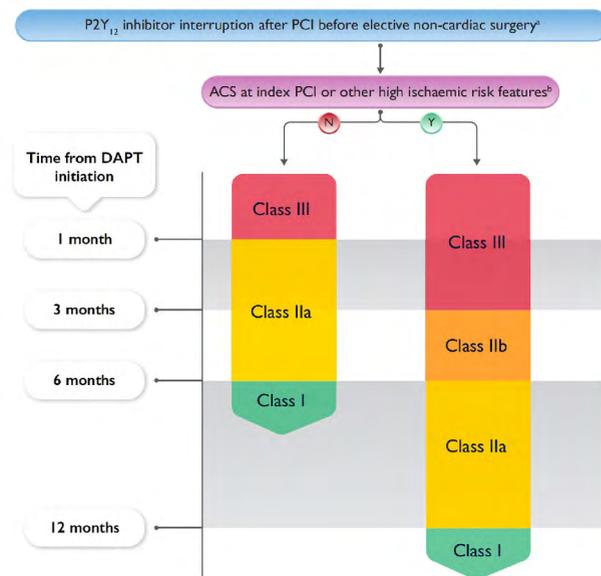


Figure 2: Latest recommendations on DAPT interruption and timing of non-cardiac surgery after coronary stenting. From 2022 ESC Guidelines on cardiovascular assessment and management of patients undergoing non-cardiac surgery. *Eur Heart J.* 2022 Oct 14;43(39):3826-3924.

Using Artificial Intelligence to Improve Patient Outcomes

JEFFREY BANDER, MD

Artificial intelligence (AI) is revolutionizing the field of cardiology and will improve patient care in several ways. One of the most significant ways that AI is impacting cardiology is by helping doctors to make more accurate diagnoses and treatment plans for patients.

One of the promising ways that AI is being used in cardiology is by applying machine learning algorithms. These algorithms can analyze large amounts of data, such as patient medical records and imaging studies, and identify patterns that may indicate a particular condition or disease. This can help doctors to more quickly, to accurately diagnose conditions such as heart disease or arrhythmias, and to develop more effective treatment plans.

Another way that AI is improving patient care in cardiology is by helping doctors to better understand and predict the progression of disease. For

example, AI-powered tools can analyze data from patients' medical records and imaging studies, and then use this information to create detailed models of how a particular condition may progress over time. This can help doctors to better understand the natural history of a disease and to predict with greater accuracy which patients are at high risk of developing complications.

In addition to helping doctors to make better diagnoses and treatment plans, AI is also being used to improve the delivery of care itself. For example, AI-powered tools can be used to monitor patients remotely and to alert doctors to potential problems before they become serious. This can help to improve the continuity of care and to reduce the need for hospitalization.

AI is also being used to improve the safety and efficacy of procedures, such as heart surgeries and catheterizations. AI algorithms can analyze real-time data during

AI is improving patient care in cardiology by helping doctors to make more accurate diagnoses and treatment plans, by helping to predict the progression of disease, by improving the delivery of care, and by making care more efficient.

procedures, such as images and vital signs, and use this information to guide the procedure and identify potential complications early. This can help to improve outcomes for patients and to reduce the risk of complications.

AI is also being used to improve the efficiency of care delivery. For example, AI algorithms can be used to automate routine tasks, such as scheduling appointments and ordering tests, which can free doctors and nurses to spend more time with patients.

Overall, AI is improving patient care in cardiology by helping doctors to make more accurate diagnoses and treatment plans, by helping to predict the progression of disease, by improving the delivery of care, and by making care more efficient. As AI technology continues to evolve and become more sophisticated, it is likely to have an even greater impact on the field of cardiology and on patient care.

Shock Team and MCS App

GREGORY SERRARO, MD

Cardiogenic shock, a condition in which the heart becomes unable to effectively pump blood to all of the organs in the body, has historically been difficult to treat and associated with poor patient outcomes. This condition may develop as a result of a major heart attack or chronic heart failure. Recent data has shown that when a dedicated team of specialists work together to treat patients with cardiogenic shock, patients are more likely to survive, recover and return to their previous quality of life(1, 2).

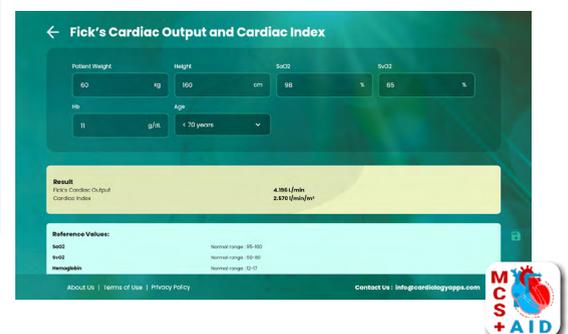
Since 2019, The Mount Sinai Hospital has emulated this approach, with dedicated specialists from interventional cardiology, advanced heart failure cardiology, cardiothoracic surgery and cardiac critical care medicine working together to treat patients

with cardiogenic shock. This team uses specialized medications and pumps, inserted without the need for open heart surgery, to support the heart as it recovers. Our team members are experts in the implantation and management of such devices including the intra-aortic balloon pump, microaxial flow catheter (Impella), left atrial-femoral artery bypass (TandemHeart) and extracorporeal membrane oxygenation. In some situations, the heart is unable to recover and, when necessary, members of the team can safely perform open heart surgery to place a permanent pump in the heart known as a left ventricular assist device (LVAD) or perform heart transplantation.

This team is on call 24 hours a day and 7 days per week for the Mount Sinai Catheterization

Our team members are experts in the implantation and management of such devices including the intra-aortic balloon pump, microaxial flow catheter (Impella), left atrial-femoral artery bypass.

Laboratory and has successfully treated hundreds of patients since its development, with a survival rate of more than twice the national average. The team is also available to other hospitals that wish to transfer a patient to The Mount Sinai Hospital for the team's expert care. This year, the team developed and released an application-based educational tool called MCS-AID to share its protocols with those who are treating cardiogenic shock and developing cardiogenic shock centers.



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Diagnosis and Management of Deep Venous Disease

VISHAL KAPUR, MD

The venous system is responsible for all the blood flow back to the heart both from both the upper and lower half of the body. There are two sets of veins which are responsible for the blood—superficial and the deep veins. The deep veins are responsible for carrying the major amount of blood to the body hence any issues with blood flow in this system can cause clinical and in some cases life threatening complications. Deep venous disease is a spectrum of disease that involves the deep veins (major veins) of the body and it includes deep venous thrombosis (DVT) and deep venous compression syndrome.

Deep Venous Thrombosis (DVT)

This is a clinically important and possible catastrophic disease process where there is a formation of clot in the deep veins—more commonly in the lower legs. The causes of clot formation can be multiple including after long distance travel, prolonged immobilization such as after surgery, hematological disorders and in some cases unknown. The diagnosis is made primarily by venous ultrasound which is a

noninvasive procedure. Treatment includes medical and endovascular intervention depending on the clinical presentation and clot burden. Medical treatment is prescribed to everyone (unless contraindicated) which includes anticoagulation with new agents known as direct oral anticoagulation (DOACS). Endovascular treatment is reserved for patients who are presenting with acute large clot burden involving mostly Iliac and femoral veins and have worsening symptoms such as impending venous phlegmasia. The idea is to access the diseased vein and clear the clot out by using various aspiration devices and in some cases lysis of the clot by infusing clot busting agents. We at The Mount Sinai Hospital specialize in endovascular therapy of clots.

Deep Venous Compression

This is a clinical syndrome where the major veins in the pelvic region can get compressed due to anatomical location of adjacent artery thereby cause impaired blood flow back to the heart. The left leg is usually involved and the presenting signs and symptoms include swelling, pain, heaviness, cramps usually only one leg and in advanced cases can cause skin

Deep venous disease is a spectrum of disease that involves the deep veins (major veins) of the body and it includes deep venous thrombosis (DVT) deep venous compression syndrome.

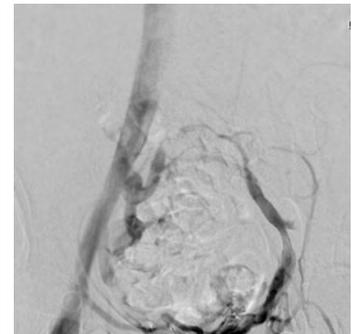


Figure 1: Occluded Left Common and External Iliac Vein.

changes such as discoloration and ulceration. The diagnosis is primarily made by intravenous ultrasound. The main vein of the leg (femoral) vein is accessed under local anesthesia and a small ultrasound is introduced into the vein. The area of compression is identified and calculated and if found significant, a stent is placed in the vein which facilitates the expansion of the vein and hence improves blood flow back to the heart. This is reserved for patients who have failed medical therapy.

At Mount Sinai, we provide state-of-the-art comprehensive management including diagnosis and treatment of various vascular diseases under one roof.

Diagnosis and Treatment of Peripheral Arterial Disease

RAMAN SHARMA, MD

Peripheral arterial disease (PAD) remains a major health risk to the population and continues to be an impactful economic burden worldwide. It is well known that patients with coronary arterial disease and peripheral arterial disease share the most common risk factors, such as diabetes mellitus, hypertension, hyperlipidemia, as well as a smoking history (both active and former).

Diagnosis of PAD is based on a combination of history, physical exam findings and noninvasive testing. Patients may complain of pain on exertion in the legs, described as a dull, aching, or fatiguing sensation after a predictable distance that also relieves with rest. Some patients, with much more advanced PAD, have already progressed at the time of presentation to critical limb threatening ischemia (CLTI), with symptoms of ischemic pain at rest or even perhaps nonhealing ischemic ulcers.

Coupled with physical exam findings of diminished peripheral pulses, cool feet, dependent rubor or ulcers, noninvasive testing helps guide the next steps of treatment. Arterial duplex ultrasonography in conjunction with arterial brachial

index (ABI) measurements at rest or after walking on a treadmill help identify not only the presence of PAD a patient, but also the level(s) where the disease is the most significant. For some patients, however, the ABI measurements may have to be performed with the patient walking on a treadmill to demonstrate hemodynamically significant PAD. Computed tomography angiography (CTA) or magnetic resonance angiography (MRA) are also often used to provide even more detailed imaging, which is instrumental in complex aortoiliac occlusive disease.

Minimally invasive treatment with the latest innovative technologies are at the forefront of endovascular intervention in treatment of PAD. With an armamentarium of dedicated atherectomy and thrombectomy devices, we are able to physically remove plaque and thrombus from the arteries, allowing for delivery of drug-coated balloons and stents, which have become the mainstay of treatment of PAD, due to their benefit as well as excellent patency rates become the mainstay of treatment of PAD with multiple randomized controlled

Diagnosis of peripheral arterial disease is based on a combination of history, physical exam findings as well as noninvasive testing.

trials demonstrating their benefit as well as excellent patency rates at five years compared to non-drug technologies.

The Mount Sinai Heart Endovascular Division continues to be at the forefront of clinical research to even further improve the treatment of PAD. As top enrollers in multiple international, randomized controlled trials, we have firsthand experience with the newest technologies available. With all aspects of PAD, from diagnosis to treatment to pioneering new technologies, we strive to treat all PAD patients with a purely endovascular, nonsurgical, approach with the best data-driven treatment strategies to improve mortality, patency and overall quality of life.

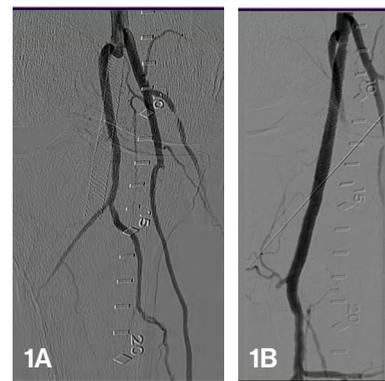


Figure 1A: Thrombotic occlusion of right popliteal stent of patient presenting with acute limb ischemia

Figure 1B: Final angiographic results after mechanical thrombectomy, atherectomy, DCB and Supera stenting.

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Interventional Fellowship Corner: How to Keep Energized and Motivated During a Busy Fellowship

RAJEEV SAMTANI, MD, VISHAL DHULIPALA, MD

“How much you put in is what you get out.”

The above proverb is true in many cases, and at The Mount Sinai Cardiac Catheterization Laboratory, we get back more than we put in. It is a gold mine for educational opportunities and the highest standards of work performance. At the commencement of the fellowship, we hesitated to take up the daunting responsibilities and concomitant challenges for one year. As we were experiencing the Fellowship, many intervening factors and the environment we felt toward the end were among the most fruitful experiences that will be remembered in our lives.

The focus on well-being is a multi-dimensional perspective here. We have bi-weekly group well-being sessions with an expert consultant.

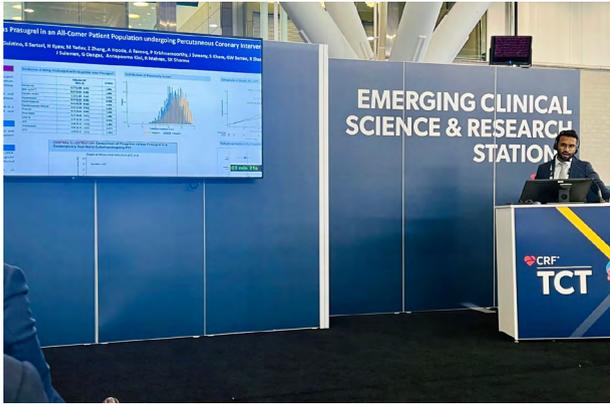
A meticulous work ethic from peers demands withstanding and balancing many factors of strategic and instant planning, communication, cooperation, efficiency, effectiveness, and good results. On the other hand, the challenging demands and stress are optimized and balanced with supportive interventions. Achievements are rewarding and thereby reduce negative stress. The collegiality of 16 Fellows acts as a stress buster from planning interventions to playing ping-pong in the fellows' lounge.

Annapoorna Kini, MD, Director of the Cardiac Catheterization Laboratory, is a strong proponent of healthy physical and mental well-being. We practice yoga as a team, and it helps us rejuvenate energy. The professional amalgam with a spectrum of experts and world-

Optimizing the time between the cases and sharing information about the happenings and what is to be done enriches the work and outcome.

renowned operators is a great opportunity to build outstanding Fellows. Complex cases are attended with great team spirit and a sense of accomplishment. The leadership pushes for nutritional well-being and sponsors fellows' great lunches. Speaking with patients in between cases, understanding them, and realizing their satisfaction is a great motivator.

The Imaging and Research team's input and support strengthen the performance and better outcomes. Optimizing the time between the cases and sharing information about the happenings and what is to be done enriches the work and outcome. The collegial hangouts arranged in New York City cushion work demands, fostering better work and social relations and promoting cohesion and well-being.



Research and Clinical Trials

Study Title	Study Details	Sponsor	Principal Investigator(s) at MSH	Target Enrollment and Study Sites	Current Status/ Enrollment at MSH
YELLOW III Trial	Effect of Evolocumab on coronary plaque characteristics: a multimodality imaging study	Amgen	A. Kini	130 USA MSH	Completed Enrollment and Follow-up of 110 pts
Protect IV Trial	Impella®-Supported PCI in High-Risk Patients With Complex Coronary Artery Disease and Reduced Left Ventricular Function: The PROTECT IV Trial	Abiomed Inc.	S. Sharma	1,252 (Global) 120 centers	Ongoing/ 37 randomized and 11 in registry
Triluminate Study	Trial to Evaluate Treatment With Abbott Transcatheter Clip Repair System in Patients With Moderate or Greater Tricuspid Regurgitation (TRILUMINATE)	Abbott Laboratories	G. Tang	450 (Global) 30 Centers	Completed/12 randomized and 3 roll-ins
ACURATE IDE Trial	ACURATE IDE: Transcatheter Replacement of Stenotic Aortic Valve Through Implantation of ACURATE in Subjects INdicatEd for TAVR	Boston Scientific Corp.	A. Kini	640 (USA) 80 centers	Ongoing/ 16 subjects enrolled
SMART Trial	SMall Annuli Randomized To Evolut™ or SAPIEN™ Trial	Medtronic PLC	S. Sharma	700 (USA) 60 centers	Ongoing/ 22 subjects enrolled

Study Title	Study Details	Sponsor	Principal Investigator(s) at MSH	Target Enrollment and Study Sites	Current Status/ Enrollment at MSH
COSIRA-II Trial	Efficacy of the COronary Sinus Reducer in Patients with Refractory Angina II (COSIRA-II)	Neovasc Medical Inc.	S. Sharma	380 (USA) 50 centers	Ongoing/ 4 subjects enrolled
MITRACLIP EXPAND G4 Study	MitraClip Expand G4: A Post-Market Study Assessment of the Safety and Performance of the MitraClip G4 System	Abbott Laboratories	A. Kini	1,060 (USA) 60 centers	Ongoing/ 23 subjects enrolled
ROTACUT Trial	ROTACUT: Rotational Atherectomy combined with cutting balloon to optimize stent expansion in calcified lesions	Boston Scientific Corporation	S. Sharma	60 (USA) 2 centers	Ongoing/40 subjects enrolled
LIFE-BTK Study	LIFE-BTK Study is to evaluate the safety and efficacy of the ESPRIT BTK Everolimus-Eluting Bioresorbable Scaffold System for treatment of narrowed arteries in CLI patients	Abbott Laboratories	P. Krishnan	600 (USA) 30 centers	Ongoing/19 subjects enrolled
MOTIV BTK RTC Trial	MOTIV BTK RTC Trial evaluates the use of the MOTIV Sirolimus-Eluting Bioresorbable Vascular Scaffold in patients suffering from CLI	REVA Medical	P. Krishnan	300 (USA) 20 centers	Ongoing/ 2 subjects enrolled

Top Ten Major Publications of 2022



1. Bivalirudin Plus a High-Dose Infusion Versus Heparin Monotherapy in Patients With ST-Segment Elevation Myocardial Infarction Undergoing Primary Percutaneous Coronary Intervention: A Randomised Trial

Li,Zhenyang Liang,Lei Qin,Mian Wang,Xianzhao Wang,Huanyi Zhang,Yin Liu,Yan Li,Zhisheng Jia,Limin Liu,Hongyan Zhang,Jun Luo,Songwu Dong,Jincheng Guo,Hengqing Zhu,Shengli Li,Haijun Zheng,Lijun Liu,Yanqing Wu,Yiming Zhong,Miaohan Qiu,Yaling Han et al. Bivalirudin plus a high-dose infusion versus heparin monotherapy in patients with ST-segment elevation myocardial infarction undergoing primary percutaneous coronary intervention: a randomised trial. *Lancet* 2022 November 6; 400: 1847–57. doi:10.1016/S0140-6736(22)01999-7.

This large-scale trial examining bivalirudin with a post-PCI high-dose infusion compared with heparin alone, the regimens that previous studies have shown to have the best balance of safety and efficacy. In patients with STEMI undergoing primary PCI predominantly with radial artery access, anticoagulation with bivalirudin plus a post-PCI high-dose infusion for 2–4 h significantly reduced the 30-day composite rate of all-cause mortality or BARC types 3–5 major bleeding compared with heparin monotherapy.



2. Coronary In-Stent Restenosis: JACC State-of-the-Art Review

Gennaro Giustino, Antonio Colombo, Anton Camaj, Keisuke Yasumura, Roxana Mehran, Gregg W. Stone, Annapoorna Kini, and Samin K. Sharma. *J Am Coll Cardiol*. 2022 Jul, 80 (4) 348–372.

Comprehensively reviewed the incidence, mechanisms, and imaging characterization of ISR and propose a contemporary treatment algorithm.



3. Ticagrelor vs Prasugrel in a Contemporary Real-World Cohort Undergoing Percutaneous Coronary Intervention

Koshy A, Giustino G, Sartori S, et al. Ticagrelor vs Prasugrel in a Contemporary Real-World Cohort Undergoing Percutaneous Coronary Intervention. *J Am Coll Cardiol Interv*. 2022 Nov, 15 (22) 2270–2280. <https://doi.org/10.1016/j.jcin.2022.09.021>.

The authors compared the efficacy and safety of ticagrelor and prasugrel in a real-world contemporary PCI cohort. In this contemporary patient population undergoing PCI, prasugrel, and ticagrelor were associated with similar 1-year efficacy and safety.



4. Determinants of Drug-Coated Balloon Failure in Patients Undergoing Femoropopliteal Arterial Intervention

Krishnan P, Farhan S, Schneider P, Kamran H, Iida O, Brodmann M, Micari A, Sachar R, Urasawa K, Scheinert D, Ando K, Tarricone A, Doros G, Tepe G, Yokoi H, Laird J, Zeller T. Determinants of Drug-Coated Balloon Failure in Patients Undergoing Femoropopliteal Arterial Intervention. *J Am Coll Cardiol*. 2022 Sep 27;80(13):1241–1250. doi: 10.1016/j.jacc.2022.06.043. PMID: 36137674.

The authors sought to investigate the determinants of DCB failure in femoropopliteal disease. Patency loss after DCB treatment was influenced by procedural and clinical factors. Residual stenosis >30%, smaller preprocedure RVD, and higher RCC may be considered predictors of increased risk of DCB failure and its components in femoropopliteal artery disease.



5. Pathophysiology, Echocardiographic Diagnosis, and Treatment of Atrial Functional Mitral Regurgitation: JACC State-of-the-Art Review

Farhan S, Silbiger JJ, Halperin JL, Zhang L, Dukkipati SR, Vogel B, Kini A, Sharma S, Lerakis S. Pathophysiology, Echocardiographic Diagnosis, and Treatment of Atrial Functional Mitral Regurgitation: JACC State-of-the-Art Review. *J Am Coll Cardiol*. 2022 Dec 13;80(24):2314–2330. doi: 10.1016/j.jacc.2022.09.046. PMID: 36480974.

In the past decade, evidence has accrued suggesting functional MR can also be caused by left atrial enlargement. This underrecognized cause of secondary MR—atrial functional MR (AF-MR)—is mechanistically linked to annular enlargement, perturbations of annular contraction, and atrio-genic leaflet tethering. Additionally, several studies have reported reductions in MR and symptomatic improvement with restrictive annuloplasty and transcatheter edge-to-edge repair. This review discusses the pathophysiology, echocardiographic diagnosis, and treatment of AF-MR. AF-tricuspid regurgitation is also discussed.

6. Revascularization Strategies for Patients With Femoropopliteal Peripheral Artery Disease

Farhan S, Enzmann F, Bjorkman P, Kamran H, Zhang Z, Sarori S, Vogel B, Tarricone A, Linni K, Venermo M, van der Veen D, Moussalli H, Mehran R, Reijnen M, Bosiers M, Krishnan P. Revascularization Strategies for Patients With Femoropopliteal Q1 Peripheral Artery Disease Q15. *J Am Coll Cardiol*. Inprint. doi:10.1016/j.jacc.2022.10.036.

This study sought to perform a pooled analysis of individual patient data from all randomized controlled trials comparing EVT vs BSx. These findings further support the efficacy and safety of EVT as an alternative to BSx in patients with symptomatic femoropopliteal peripheral artery disease.



7. Ticagrelor Monotherapy After PCI in High-Risk Patients With Prior MI: A Prespecified TWILIGHT Substudy

Chiarito M, Baber U, Cao D, Sharma SK, Dangas G, Angiolillo DJ, Briguori C, Cohen DJ, Dudek D, Džavík V, Escaned J, Gil R, Hamm CW, Henry T, Huber K, Kastrati A, Kaul U, Kornowski R, Krucoff M, Kunadian V, Mehta SR, Moliterno D, Ohman EM, Oldroyd K, Sardella G, Zhongjie Z, Sartori S, Stefanini G, Shlofmitz R, Steg PG, Weisz G, Witzenbichler B, Han YL, Pocock S, Gibson CM, Mehran R. Ticagrelor Monotherapy After PCI in High-Risk Patients With Prior MI: A Prespecified TWILIGHT Substudy. *JACC Cardiovasc Interv*. 2022 Feb 14;15(3):282-293. doi: 10.1016/j.jcin.2021.11.005. Epub 2022 Jan 12. PMID: 35033468

The aim of this study was to evaluate if patients with prior myocardial infarction (MI) could benefit from ticagrelor monotherapy in terms of bleeding reduction without any compromise in ischemic event prevention. Ticagrelor monotherapy is associated with significantly lower risk for bleeding events compared with ticagrelor plus aspirin, without any compromise in ischemic prevention, among high-risk patients with history of MI undergoing PCI.



8. “Shaking” or “Shaving” to Treat Massive Coronary Nodular Calcification?

Yasumura K, Bagga S, Vengrenyuk Y, et al. “Shaking” or “Shaving” to Treat Massive Coronary Nodular Calcification?. *J Am Coll Cardiol Intv*. 2022 Oct, 15 (19) e209–e211. doi:10.1016/j.jcin.2022.05.049.

The treatment of complex coronary calcified lesion with nodular calcification (NC) is challenging due to its proliferative feature through the stent struts and subsequent stent failures. In this setting, extensive calcium modification is mandatory to achieve a larger lumen area. However, there is no consensus on the best treatment strategy for NC. Herein, we present two cases of intravascular imaging-guided massive NC treatment with different approaches.



9. Improved Commissural Alignment in TAVR With the Newest Evolut™ FX Self-Expanding Supra-Annular Valve: First-in-Human Experience

Khera S, Krishnamoorthy P, Sharma S, et al. Improved Commissural Alignment in TAVR With the Newest Evolut FX Self-Expanding Supra-Annular Valve. *J Am Coll Cardiol Intv*. null2022, 0 (0). doi:10.1016/j.jcin.2022.10.041.

In our early experience with the Evolut FX system, the new design features appeared to significantly improve the ability to achieve commissural alignment and achieve more predictable and symmetrical final implantation (less pivoting on release). The findings of our first-in-human series require validation in a larger, multicenter study, which is currently ongoing.



10. Guided and Unguided De-Escalation from Potent P2y12 Inhibitors Among Patients with Acute Coronary Syndrome: a Meta-Analysis

Tavenier AH, Mehran R, Chiarito M, Cao D, Pivato CA, Nicolas J, Beerkens F, Nardin M, Sartori S, Baber U, Angiolillo DJ, Capodanno D, Valgimigli M, Hermanides RS, van 't Hof AWJ, Ten Berg JM, Chang K, Kini AS, Sharma SK, Dangas G. Guided and unguided deescalation from potent P2Y12 inhibitors among patients with acute coronary syndrome: a meta-analysis. *Eur Heart J Cardiovasc Pharmacother*. 2022 Aug 11;8(5):492-502. doi: 10.1093/ehjcvp/pvab068. PMID: 34459481

Various DAPT de-escalation strategies, defined as switching from a full-dose potent to a reduced dose or less potent P2Y12 inhibitor, have been evaluated in several ACS-PCI trials. We aimed to compare DAPT de-escalation to standard DAPT with full-dose potent P2Y12 inhibitors in ACS patients who underwent PCI. De-escalation of DAPT after PCI for ACS, both unguided and guided by genetic or platelet function testing (PFT), was associated with lower rates of clinically relevant bleeding and ischemic events as compared to standard DAPT with potent P2Y12 inhibitors based on five open-label RCTs reviewed.





Samin K. Sharma, MD, FACC, MSCAI

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 Senior Vice President, Operations and Quality, Mount Sinai Heart
 Director, Interventional Cardiology, Mount Sinai Health System
 President, Mount Sinai Heart Network
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Clinical Interests:

Coronary Artery Disease
 Interventional Cardiology
 Atherectomy
 Valvular Intervention

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Samir K. Sharma, MD, is a renowned interventional cardiology expert well known for performing high-risk complex coronary interventions (more than 1,500 interventions per year) with an extremely high success rate (greater than 99 percent) while achieving an extremely low major complication rate (less than 0.2 percent). He has received the prestigious two-star designation (significantly lower than expected mortality) numerous times from the New York State Department of Health, and the Governor's Award of Excellence in Medicine in 1996. He served on New York State's Cardiac Advisory Board from 2004–2016.

He served on New York State's Cardiac Advisory Board from

2004–2016. Under Dr. Sharma's leadership, The Mount Sinai Hospital Cardiac Catheterization Laboratory has become one of the safest and busiest centers in New York, providing state-of-the-art cardiac and interventional care for all types of simple and complex heart patients. Dr. Sharma specializes in the nonsurgical treatment of mitral and aortic valve disease, including transcatheter aortic valve replacement (TAVR) and MitraClip™ procedures (TEER).

He has been dubbed "master of the Rotablator" and is regularly featured on national and local TV (recently on CBS, TV Asia), and in newspapers and magazines including *Newsday*, *Newsweek*, *The New York Times*, *The New York Post*, *Forbes*, *The Wall Street Journal*, *The New York Daily News*, *The Washington Post*, *New York Magazine*, *India Abroad*, and *India Today*. He has received numerous awards: 2023 Master Operator by India Live Conference, 2021-2022 Chief Guest, Times Square, Diwali Celebration; 2018 Chairman Board of Trustees, Association of Indians in America (AIA); 2015 Honorary Master of Science PhD degree by Rajasthan University Jaipur India; 2014 Distinguished Physician Scientist by AAPI-QLI for excellence in Medicine; 2011 Ellis Island Medal of Honor; 2011 American Heart Association Achievement in Cardiovascular Science & Medicine Award; 2011 American Association of Physicians of Indian Origin (AAPI)

Under Dr. Sharma's leadership, The Mount Sinai Hospital Cardiac Catheterization Laboratory has become one of the safest and busiest centers in New York, providing state-of-the-art cardiac and interventional care for all types of simple and complex heart patients.

Physician of the Year; 2010 AIA for Excellence in Medicine; 2003–2007 and 2010–2022 Best Doctors by *New York Magazine*; 2008–2022 Super Doctors; 2007 Jacobi Medallion Award by The Mount Sinai Hospital; 2007 Physician of the Year by The Mount Sinai Hospital and 2000 Simon Deck Award for Outstanding Teacher of the Year.

He has authored more than 360 papers and 16 book chapters in the field of coronary interventions, structural heart disease and safety of percutaneous interventions. He is also a philanthropist, and The Mount Sinai Hospital Cardiac Catheterization Laboratory is named the Dr. Samin K. Sharma Family Foundation Cardiac Catheterization Laboratory. Dr. Sharma has built a 250-bed heart hospital (EHCC) in his native Jaipur, India, to provide the best care to all patients irrespective of their financial and social status.

His live monthly webcast series, CCC Live Cases (www.ccclivecases.org), started in 2009, and has an audience of more than 25,000 viewers each month in 179 countries.

He also enjoys teaching other cardiologists and improving patient outcomes with his annual Complex Coronary Cases (CCC) Symposium and numerous other major scientific meetings, conferences, and live relays. He is also the Director of the Top Ten Topics in Clinical Cardiology Course every October and the NY Transcatheter Valves Symposium every December.



Annapoorna S. Kini, MD, MRCP, FACC

Director, Cardiac Catheterization Laboratory
Interventional Director, Structural Heart Program for System
Director, Interventional Cardiology Fellowship Program
Zena and Michael A. Weiner Professor of Medicine

Clinical Interests:

Intravascular Imaging

Interventional Cardiology: CTO

Valvular Intervention

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Annapoorna S. Kini, MD, is internationally acclaimed for her special expertise in performing complex coronary interventions, especially in chronic total occlusion for patients with advanced coronary artery disease, high-risk interventional cases, and alcohol septal ablation for the treatment of obstructive hypertrophic cardiomyopathy. Dr. Kini has been the principal or co-investigator in numerous randomized clinical trials. She has extensive experience with mitral and aortic balloon valvuloplasty, and has been among the first few interventional cardiologists in the country to use the transcatheter aortic valve implantation procedure in the treatment of inoperable patients with critical aortic stenosis. She has also made history by performing the

first live case performed entirely by women during the CRT meeting on March 5, 2018.

Dr. Kini performs more than 1,000 coronary interventions annually, the highest number by a female interventionist in the United States, with an extremely low complication rate of less than 0.3 percent; an official report from The New York State Department of Health recognized Dr. Kini as the safest operator among 350 other physicians in the state of New York numerous times (2004-2016). She is the recipient of 2011 Dean's Award for Excellence in Clinical Medicine at The Mount Sinai Hospital. She also received the Physician of the Year award in 2014 from The Mount Sinai Hospital nurses. She received the Excellence in Medicine Award from the National Association of Physicians of India (AAPI) in July 2016. In May 2017, she received the prestigious Ellis Island Medal of Honor, the highest award given to any immigrant civilian, and in 2018 she received the American Heart Association's Heart of Gold Award.

Dr. Kini is the recipient of the "Rock Star of Science" award from the American Heart Association. She is a member of the Royal College of Physicians of London, and Fellow of the American College of Cardiology.

The recent YELLOW III study, which was presented at ACC 2023 as a LBCT, was an ambitious translational combination of multimodality imaging with clinically relevant cellular biology and comprehensive transcriptomics

Dr. Kini performs more than 1,000 coronary interventions annually, the highest number by a female interventionist in the United States, with an extremely low complication rate of less than 0.3 percent.

to better assess the effect of evolocumab on coronary plaque morphology.

In the digital field, Dr. Kini has led the development of eight free educational applications. She has also created a mobile app-based chair yoga program for her recent SLYM II trial, and is developing a patient experience and education platform called TAVRbot for structural heart patients. Her recent STEMicathAID Piloted at Mount Sinai Queens has been working to reduce the device time to reperfusion on vulnerable heart attack patients since July of 2021.

Dr. Kini is an excellent teacher, and is dedicated to the teaching of both cardiology and interventional fellows. In fact, the 2012 batch of Mount Sinai interventional fellows created a teaching award in her name, "The Annapoorna S. Kini Fellows' Choice Award" for excellence in teaching. Her achievements are not limited to serving as the Director of the Annual Live Symposium of Complex Coronary Cases at The Mount Sinai Hospital, one of the most attended and respected meetings in the field of interventional cardiology in the country. She is also the director of a monthly webcast program, *CCC Live Cases* (www.ccclivecases.org), which started in 2009 and has an audience of more than 25,000 in 179 countries.



Prakash Krishnan, MD, FACC

Director of Endovascular Services, Mount Sinai Health System
Associate Professor of Medicine (Cardiology)
Associate Professor of Radiology

Clinical Interests:

Interventional Cardiology

Endovascular Intervention

Carotid Stenting

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Prakash Krishnan, MD, is a world-renowned expert in peripheral vascular disease and is internationally recognized as a leader in the catheter-based treatment of peripheral arterial disease. Dr. Krishnan's expertise includes nonsurgical treatment of coronary and peripheral vascular diseases, including coronary stents, peripheral vascular angioplasty and stents, atherectomy, carotid stents, renal stents, renal denervation, and complex venous disease intervention. Dr. Krishnan is a patient advocate and an educator. He has built a robust community-based outreach program that serves a vast population of patients with complex coronary and peripheral arterial disease. He also serves as the

Director of Endovascular Services for The Mount Sinai Health System. Dr. Krishnan has been educating interventionalists globally via live satellite transmissions at national and international meetings, and with his live monthly webcast program showcased on www.ccclivecases.org. He served as the co-primary investigator in the ILLUMENATE Trial and is a leading authority in the performance of nonsurgical interventions for peripheral arterial disease. He has received numerous awards and honors: in 2018, The Reverend Dr. Martin Luther King Legacy Award for Physician Services from Clergy with a Purpose. In 2022, he was also recognized for his contributions in community service and honored by the Association of Indian Americans (AIA) at their annual gala event in September 2022 and this year at UK House of Commons, British Parliament in London, he will be receiving the Bharat Gaurav Award, given to people with extraordinary excellence in their fields. In September 2022, he was also recognized for his contributions in community service and honored by the Association of Indian Americans (AIA) at their annual gala event.

He has also served as editor of numerous textbooks on endovascular interventions and has authored numerous peer-reviewed articles and book chapters. He is co-director of the annual NY Endovascular Summit (NYEVS)

Dr. Krishnan has received numerous awards and honors, most recently the Reverend Dr. Martin Luther King Legacy Award for Physician Services from Clergy with a Purpose.

and The Mount Sinai Endovascular Fellows Course.

Dr. Krishnan is an internationally established leader in education. He has been both innovative and progressive, and recognized the opportunity to reach thousands of physicians to help advance the understanding of techniques in the interventional treatment of peripheral arterial disease.

In 2012, Dr. Krishnan began to broadcast monthly Peripheral Interventions Live via CCC Live Cases, which has more than 25,000 views per month in 179 countries.

As a master educator, Dr. Krishnan started the Endovascular Fellowship program at Mount Sinai Heart in 2013. He was recognized with the Distinguished Teaching Award by the Interventional Fellows in June 2017, providing incomparable education in the field of peripheral arterial disease. The following year, he received the Mentorship in Endovascular Interventions Award by the Mount Sinai Interventional Cardiology Fellows. In 2018, he was nationally recognized by being named Co-Director of the annual Endovascular Fellows Course by SCAI (Society of Angiography and Interventions). He is currently working as the Program Director for the Women as One Foundation's Peripheral Vascular Disease Clinical Program to promote, educate, and support young women cardiologists to become leaders in the field of vascular disease and endovascular intervention.

George D. Dangas, MD, PhD, MACC, MSCAI



Director, Cardiovascular Innovation

Professor of Medicine (Cardiology)

Professor of Surgery (Vascular)

George D. Dangas, MD, performs a wide spectrum of complex cardiovascular interventional procedures to treat coronary and valvular heart disease, aortic, carotid, and peripheral arterial disease, and resistant hypertension. Dr. Dangas is a leading authority in the performance of nonsurgical cardiac and vascular interventions and in the development of innovative

approaches to treat complex problems across many specialties. He is currently a trustee of the American College of Cardiology and editor-in-chief of *CardioSource WorldNews Interventions*, and has been chair of the Interventional Scientific Council and a trustee of the Society for Cardiovascular Angiography and Interventions. He is director of the annual conferences “Transcatheter Cardiovascular Therapeutics” and “Interventional Fellows’ Courses” in the United States and Europe, and a key faculty and program committee member for multiple international conferences, including the ACCi2 Summit, ACCIS, AHA, and SCAI for many years. Dr. Dangas is the Director of Academic Affairs at the Cardiovascular Research Foundation.

He is currently the President-elect of the Society of Cardiovascular Angiography and Interventions, Chair of the AHA Laennec Society, Section Editor of the *Journal of the American College of Cardiology* and Editor-in-Chief of the 3rd Edition textbook “Interventional Cardiology Principles & Practice.” He serves as Course Director of TCT—Transcatheter Cardiovascular Therapeutics and several other national and international conferences. Dr. Dangas is a founding physician and Director of Academic Affairs of the Cardiovascular Research Foundation in New York and Adjunct Professor at the Universities of Athens and Vienna.

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Joseph M. Sweeny, MD, FACC



Medical Director, Ambulatory Cardiology Center

Associate Professor of Medicine (Cardiology)

Joseph M. Sweeny, MD, performs both diagnostic cardiac catheterization and coronary interventions. He is the principal investigator of multiple national clinical trials and is actively involved in the Interventional Cardiology Fellowship Training Program as the Associate Program Director. In 2014, he became the Medical Director of the Lauder Ambulatory

Clinical Interests:

Acute Myocardial Infarction

Fellows Education

Coronary Intervention

Cardiology Center, which provides comprehensive ambulatory care with all modalities of noninvasive cardiac testing in one central location.

With a special interest in treating post-heart transplant patients, Dr. Sweeny works closely with the Heart Transplant Team for coronary artery vasculopathy surveillance and endomyocardial biopsies in the Cardiac Catheterization Laboratory. In addition, he has a clinical interest in Coronary Microvascular Disease and Coronary Physiology Testing in the Catheterization Laboratory.

His research has focused mainly on antiplatelet therapy in the treatment of acute coronary syndromes. Dr. Sweeny serves as an assistant editor/reviewer for the *Journal of the American College of Cardiology* and was the Site Principal Investigator for the NIH-sponsored Ischemia Trial. As the associate program director for the Interventional Cardiology Fellowship program, he is actively involved in the selection, education, and mentoring of our interventional fellows.

Dr. Sweeny also serves as the Radiation Safety Officer for the Cardiac Catheterization Laboratory. In this role, he has developed protocols and processes for tracking and monitoring patient radiation dose during interventional procedures.

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Pedro R. Moreno, MD, FACC



Director of Quality Assurance for Cardiology
Director of Credentials and Promotions for Cardiology
Professor of Medicine (Cardiology)

Pedro R. Moreno, MD, performs more than 1,000 cardiac coronary invasive procedures annually (including diagnostic catheterizations, angioplasties, and coronary stents) with >99 percent success rate and <1 percent major complications.

As a world-renowned expert in atherosclerosis, Dr. Moreno has been a pioneer in the understanding of

inflammation and acute coronary syndromes. Dr. Moreno also contributed to vascular biologic aspects of restenosis, a renarrowing process that occurs in coronary or peripheral arteries after stenting.

Dr. Moreno has additional extensive experimental research in novel diagnostic and therapeutic modalities for vulnerable plaques, the most common cause of a heart attack.

Dr. Moreno is an official reviewer for the American Heart Association and several scientific journals including *Annals of Internal Medicine*, *Circulation*, *The Journal of the American College of Cardiology*, *American Journal of Cardiology*, *American Heart Journal*, and *European Heart Journal*. He is honorary member of several international cardiology organizations including the Chilean Society of Cardiology, the Venezuelan Society of Cardiology, the Colombian Society of Cardiology and the Dominican Republic Society of Cardiology. Finally, he is an excellent teacher and a mentor of clinical and research fellows at The Mount Sinai Hospital.

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Roxana Mehran, MD, FACC, FACP, FESC, MSCAI



Endowed Mount Sinai Professor in Cardiovascular Clinical Research and Outcomes

Professor of Medicine (Cardiology)

Director, Interventional Cardiovascular Research and Clinical Trials

Director, Women's Heart and Vascular Center at Mount Sinai Heart

Clinical Interests:

Antithrombotic Therapy for Secondary Prevention

Contrast-Induced Acute Kidney Injury (AKI)

Cardiovascular Disease in Women

Roxana Mehran, MD, is an internationally renowned clinical researcher in interventional cardiology. She has built a globally respected academic research center focused on developing randomized clinical

trials, outcomes research projects, and high-impact scientific publications. She has served as principal investigator for numerous global studies, regularly participates in clinical guidelines committees, and has authored >1,300 peer-reviewed articles. Dr. Mehran is a current American College of Cardiology (ACC) Board of Trustees member. She is a founder and was Chief Scientific Officer of the Cardiovascular Research Foundation (CRF). She has been repeatedly included in Clarivate Analytics: "Most Cited Researchers—Top 1%" and "The World's Most Influential Scientific Minds" (Thomson Reuters).

Dr. Mehran is leading the Lancet Women and CVD Commission, bringing together leading researchers from around the world to identify and address gaps in research and care for women with CVD. She was named Director of the Women's Heart and Vascular Center at The Mount Sinai Hospital, spearheading a program that represents a collaboration across disciplines designed to meet the unique needs of women's cardiovascular health. In 2019, she founded Women as One, dedicated to advancing opportunities for women in medicine.

Dr. Mehran is recipient of numerous awards, including the 2016 ACC Bernadine Healy Leadership in Women's CVD award, the 2018 Nanette Wenger Award for Excellence in Medical Leadership, the 2019 Ellis Island Medal of Honor, and the 2019 ESC Silver Medal and Andreas Grüntzig Lecture plaque. Most recently, she received the 2022 AHA Women in Cardiology Mentoring Award; and 2022 CRF Pulse-Setter Champion Award.

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Vishal Kapur, MD, FACC, FSCAI, RPVI



Director of Endovascular Services, Mount Sinai Morningside

Assistant Director, Endovascular Services, The Mount Sinai Hospital

Assistant Professor of Medicine (Cardiology)

Vishal Kapur, MD, is an interventional and endovascular cardiologist. He is board certified in the fields of cardiology, interventional cardiology, vascular medicine, and endovascular medicine, and has trained with world renowned experts in the field. He is an expert in catheter-based vascular therapy, specializing in

endovascular management of acute and chronic arterial and venous disease. He is proficient in procedures such as coronary angioplasty, stenting, rotational atherectomy, angioplasty-stenting of carotid, renal, subclavian, mesenteric, Iliac, and lower extremities, IVC filter placement, thrombolysis, rheolysis thrombectomy in the management of acute limb ischemia, and deep vein thrombosis. He is also trained in performing venous ablation and sclerotherapy in the management of reticular and varicose veins.

Dr. Kapur is an excellent teacher and educator with keen interest in complex coronary interventions and peripheral endovascular interventions. He has published numerous research articles in peer-reviewed renowned medical journals and written text book chapters. His research work has been presented at national and international meetings and he has been a co-investigator in various multi-center trials. Dr. Kapur remains committed to the field of cardiology and has an unrelenting dedication toward being an outstanding clinician, researcher, and teacher.

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Jeffrey Bander, MD, FACC



Chief of Cardiology, Mount Sinai West

Medical Director, Network Development, Mount Sinai Hospital Network

Associate Professor of Medicine (Cardiology)

Jeffery Bander, MD, has pursued many areas in the health care industry after attending Harvard Medical School and MIT. One of those areas has been as a health care entrepreneur. Dr. Bander founded two successful health care companies, Providerloop and Referwell, both of which

have continued to grow. Dr. Bander's role as Medical Director of Network Development at The Mount Sinai Hospital has allowed him to collaborate with many departments to help grow and increase efficiency. While still maintaining these roles, Dr. Bander is now Chief of Cardiology at Mount Sinai West. With Dr. Bander's experience in many facets of the health care system, from practicing medicine, running departments, and fundraising, to excelling in health care finance and information technology, he seeks to build and develop the health care system to create a more efficient and effective organization to treat patients and save lives.

Dr. Bander is currently working to create a large integrated research program at Mount Sinai West focusing on technology and artificial intelligence to advance cardiovascular care.

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Malcolm Anastasius, MD



Assistant Professor of
Medicine (Cardiology)

Clinical interests: Cardiovascular
Imaging (echocardiography/cardiac
CT and MRI), Imaging for Structural
Heart Interventions

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Clinical interests:
Clinical Cardiology, Cardiac
Catheterization, Nuclear Cardiology

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Nitin Barman, MD



Director, Cardiac
Catheterization Laboratory,
Mount Sinai Morningside
Assistant Professor of
Medicine (Cardiology)

Clinical interests: Clinical
Cardiology, Transradial Intervention,
AMI Intervention, Complex Coronary
Interventions

212-523-1094 | nitin.barman@mountsinai.org

Srinivas Duvvuri, MD, FACC



Clinical Associate Professor
of Medicine (Cardiology)
Network Senior Medical
Director, Staten Island
Director, Coronary
Intervention at Richmond
University Medical Center

Clinical interests: General
Cardiology, Cardiac Catheterization,
Interventional Cardiology, Trans-radial
Intervention

718-981-2684 | srinivas.duvvuri@mountsinai.org

Serdar Farhan, MD, FESC, FACC



Assistant Professor of
Medicine (Cardiology)

Clinical interests: Cardiovascular
Imaging (echocardiography/cardiac
CT and MRI), Imaging for Structural
Heart Interventions

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Lynne Glasser, MD



Director, Interventional Inpatient
Service
Assistant Professor of
Medicine (Cardiology)
Clinical interests: Clinical
Cardiology, Preventive Cardiology,
Inpatient Cardiology

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

212-241-4521 | lynne.glasser@mountsinai.org

Sunny Goel, MD, FACC, FSCAI



Assistant Professor of
Medicine (Cardiology)

Clinical interests: Complex
Coronary Interventions, Primary
PCI, Transcatheter Aortic Valve
Replacement (TAVR), MitraClip™

917-280-6832 516-632-3672 (Mount Sinai South Nassau)
falcardiology@gmail.com

Amit Hooda, MD, FACC, FSCAI



Assistant Professor of
Medicine (Cardiology)

Assistant Director, Interventional
Cardiology Fellowship Program

Clinical interests: Complex Coronary
Interventions, AMI Intervention,
Intravascular Imaging, Transcatheter
Aortic Valve Replacement, MitraClip

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Yumiko Kanei, MD, FACC, FSCAI



Associate Program Director,
Cardiology Fellowship, MSBI
Associate Professor of
Medicine (Cardiology)

Clinical interests: Percutaneous
Coronary Intervention, Acute
Coronary Syndrome, Valvular heart
Disease

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Sahil Khera, MD, MPH, FACP, FACC, FSCAI



Interventional Director,
Structural Heart Disease
Program, MSH

Physician Lead, ADS Cardiology
Inpatient Service, MSH
Assistant Professor of
Medicine (Cardiology)

Clinical interests: TAVR, TMVR,
Complex Coronary Interventions, ASD/
PFO Closure, Left Atrial Appendage
Occlusion (LAAO)

212-241-7250 (O) / 914-564-7587 (C) | sahil.khera@mountsinai.org

Stamatios Lerakis, MD, PhD, FACC, FASE, FSCCT



Director, Noninvasive Cardiology
Director of Imaging for Structural
and Valve Interventions,
Mount Sinai Health System
Professor of Medicine (Cardiology)

Clinical interests: Cardiovascular
Multimodality Imaging, Multimodality
Imaging for Structural Heart Interventions,
Echocardiography, CMR, Cardiac CT,
Nuclear Cardiology, 4D ICE

212-241-1002 | stamatios.lerakis@mountsinai.org

Parasuram Melarcode Krishnamoorthy, MD, FACC, FSCAI



Associate Director, Structural
Heart Disease Program
Assistant Professor of
Medicine (Cardiology)

Medical Director, Cardiac Cath
Lab, Brooklyn Hospital Center
Associate Program Director,
Mount Sinai Brooklyn Hospital
Center Cardiology Fellowship

Clinical interests: Complex Coronary
Interventions, Transcatheter Aortic Valve
Replacement, Transcatheter Mitral Valve Repair/
Replacement, Transcatheter Tricuspid Valve
Repair, Paravalvular Leak Closure, ASD/PFO
Closure

732-501-5100 | parasuram.melarcode-krishnamoorthy@mountsinai.org

Isha Ranadive, MD, MPH



Assistant Professor of
Medicine (Cardiology)

Clinical interests: Clinical
Cardiology, Complex Coronary
Interventions, Primary PCI, AMI
Intervention

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Raman Sharma, MD, FACC, RPVI



Assistant Director, Endovascular
Interventions Program

Assistant Professor of
Medicine (Cardiology)

Clinical interests: Peripheral Arterial
Disease, Endovascular Intervention,
Critical Limb Threatening Ischemia,
Complex Coronary Interventions,
Venous Disease and Intervention,
Carotid Artery Stenting

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William Schwartz, MD, FACC



Clinical Director of
Ambulatory Cardiology at
Mount Sinai Queens

Assistant Clinical Professor
of Medicine (Cardiology)

Clinical interests: Clinical
Cardiology, Noninvasive Cardiology,
Cardiac Catheterization

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Joshua Shatzkes, MD, MS



Director of Ambulatory Care,
Cardiovascular Institute
at Mount Sinai West

Medical Director of Community
Outreach, Mount Sinai Network

Associate Professor of
Medicine (Cardiology)

Clinical interests: Cardiovascular
Disease Prevention, Noninvasive
Cardiovascular Imaging, Peripheral
Arterial Disease, Hypertension,
Cholesterol

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Gregory Serrao, MD, MSE



Director, Mechanical
Circulatory Support,
Cardiac Cath Lab

Assistant Program Director,
Cardiovascular Disease
Academic Track

Clinical interests: Cardiogenic
Shock, Mechanical Circulatory
Support, Cardiac Catheterization

917-756-6852 | gregory.serrao@mountsinai.org

Michael Alan G. Sicat, MD



Assistant Professor of
Medicine (Cardiology)

Clinical interests: Clinical
Cardiology, Echocardiography,
Cardiac Catheterization

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Javed Suleman, MD, FACC



Associate Clinical Professor
of Medicine (Cardiology)

Clinical interests: Clinical
Cardiology, Coronary Intervention,
Primary PCI

718-297-0440 | javed.suleman@mountsinai.org

Gilbert Tang, MD, MSc, MBA, FRCSC, FACC, FSCAI



Surgical Director, Structural
Heart Program, Mount
Sinai Health System

Professor of Cardiovascular
Surgery

Clinical interests: Transcatheter
Aortic and Mitral Valve Therapy,
Transcatheter Tricuspid Repair

646-761-0391 | gilbert.tang@mountsinai.org

VOLUNTARY ATTENDINGS

Karthik Gujja, MD, MPH



Director, Endovascular
Services at Mount
Sinai South Nassau

Assistant Professor of
Medicine (Cardiology)

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

646-584-6460 | karthik.gujja@mountsinai.org

Choudhury M. Hasan, MD, FACC, FSCAI



Associate Clinical Professor
of Medicine (Cardiology)

Clinical interests: Cardiac
Catheterization, Coronary
Interventions, Echocardiography

718-657-8001 | cmmhasan03@gmail.com

Haroon Kamran, MD, FACC, FSCAI



Assistant Clinical Professor
of Medicine (Cardiology)

Clinical interests: Clinical Cardiology,
Interventional Cardiology, Peripheral
Endovascular Intervention

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José Meller, MD



Clinical Professor of
Medicine (Cardiology)

Clinical interests: Clinical
Cardiology, Fellows Education,
Cardiac Catheterization

212-988-3772 | josemeller44@gmail.com

Vinod Patel, MD, FACC, FSCAI



Assistant Clinical Professor
of Medicine (Cardiology)

Clinical interests: Noninvasive
Cardiology, Cardiac Catheterization,
Peripheral Vascular Interventions

718-788-1688 | drvinodpatel@gmail.com

Beth Oliver, DNP, RN, FAAN



**Chief Nurse Executive
Senior Vice President,
Cardiac Services
Mount Sinai Health System**

Dr. Oliver is responsible for the practice of nursing across Mount Sinai Health System. A nationally recognized cardiovascular leader, her top priorities are ensuring quality care for patients, advancing the professional development of nurses, transforming the care we provide around the needs of our patients and communities, and partnering on our transition from volume to value. For more than 28 years, Dr. Oliver has been a transformational cardiac nurse leader at The Mount Sinai Hospital, most recently serving as Senior Vice President of Cardiac Services for the Health System.

**212-241-0796
beth.oliver@mounsinai.org**

Thomas Geramita, PA-C



**Associate Director, Clinical
Operations of Cardiac
Catheterization Laboratory and
Advanced Practice Providers**

Thomas Geramita started as a Senior Physician Assistant (PA) in the department of Electrophysiology here at The Mount Sinai Hospital in October 2019. During his time as a Senior PA he began to develop process improvement and initiatives which led to an interest in leadership and an eventual promotion as the Advanced Practice Provider (APP) supervisor at Mount Sinai Heart. As the APP supervisor he led quality initiatives, standardized orientation, and initiated an APP focused cardiac educational lecture series which resulted in a promotion to an Associate Director. As Associate Director, he directs, oversees, and coordinates all administrative and clinical operations for the Cardiac Catheterization Laboratory and apps of Mount Sinai Heart.

**212-241-7114
thomas.geramita@mounsinai.org**

**Jeannie Banton MBA,
MSN, CCRN, RN-BC**



**Clinical Nurse Manager
Cardiac Catheterization and
Electrophysiology Laboratory**

Jeannie Banton started in The Mount Sinai Hospital Cardiac Catheterization Laboratory in 2012 as a Staff Nurse. After obtaining her Master's in Nursing Administration and Informatics in 2021, she transitioned to the role of Nurse Manager for The Mount Sinai Hospital's Cardiac Catheterization and Electrophysiology Laboratory, overseeing and coordinating administrative and clinical operations.

**212-241-2926
jeannie.banton@mounsinai.org**



NURSE PRACTITIONER TEAM

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



Maryam Akhtar



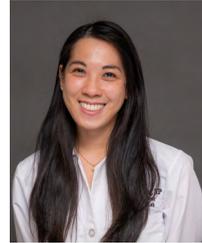
Norwin Bunal



Melissa Chang



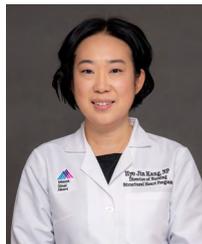
**Aira Fides
Gonzales**



Michelle Hang



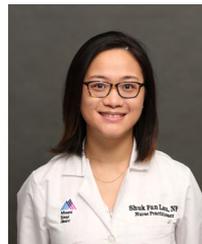
Kristina Hartig



Hyo Jin Kang
Clinical Director,
Structural Heart Program



Rheoneil Lascano



**Shuk Fan
Lau-Mckee**



Dana Leichter



Jessica Lim



Nelya Lozynska



Derek Pineda



**Supawadee
Pitakmongkolkul**



Leah Riggs Capra



Aanal Shah



Indra Sinanan



Richard Ternemille



Shira Wender



Kevin Williams

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.



Ibrahim Ali, MD



Ayush Arora, MD



Vishal Dhulipala, MD



Ali Farooq, MD



Gennaro Giustino, MD



Osman Jaffer, MD



Udit Joshi, MD



Mahin Khan, MD



Anoop Koshy, MD



Yoav Niv Granot, MD



Sagar Ranka, MD



Negar Salehi, MD



Rajeev Samtani, MD

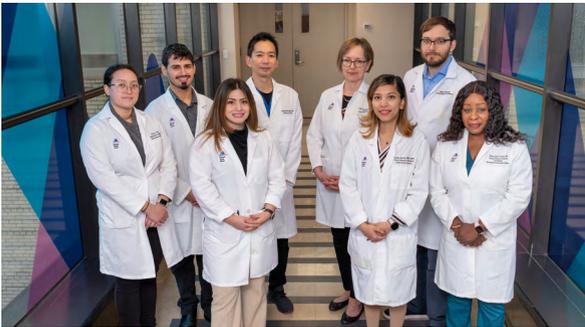


Richard Tanner, MD



Manish Vinayak, MD

NURSE PRACTITIONER TEAM



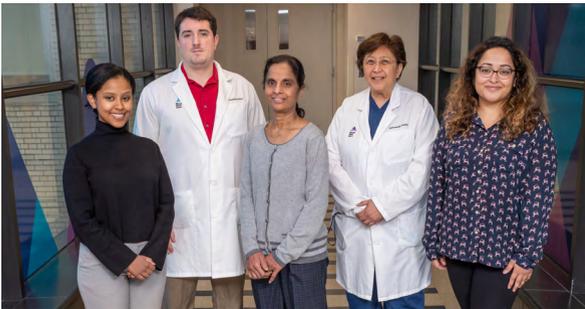
Research Team

From left: Riela Popp, Jaime Gonzalez, Angela Bustamente, Shingo Minatoguchi, Yuliya Vengrenyuk, Nimisha Baruah, Andriy Vengrenyuk, Nicole Saint Vrestil



Supporting Staff

Jasmin Jordan, Juanita Jordan, Celeste Caro, Carol Henry, Era Zuberko, Maria Directo, Chitra Singh



Interventional Database Team

Lydia Fikru, Kevin Dellner, Roja Thapi, Elena Ramos, Pooja Vijay



Structural Heart Team

Shuk Fan Lau-Mckee, Angela Gratereaux, Dana Leichter, Hyo Jin Kang, Jancin Robinson, Maryam Akhtar, Adriana Bautista, Derek Fernandez

Achievements

1 Castle Connolly Top Doctors



Samin K. Sharma, MD
 Annapoorna S. Kini, MD
 Prakash Krishnan, MD
 Pedro Moreno, MD
 Roxana Mehran, MD

George Dangas, MD
 Joseph Sweeny, MD
 William Schwartz, MD
 Jeffrey Bander, MD

2 New York Magazine Best Doctors



Samin K. Sharma, MD (13 times in 18 years)	Roxana Mehran, MD (7 times in 9 years)
Annapoorna S. Kini, MD (5 times in 6 years)	Joseph Sweeny, MD (2nd year)
Prakash Krishnan, MD (2nd year)	William Schwartz, MD (5 times in 14 years)
George Dangas, MD (8 times in 9 years)	Gregg Stone, MD (7 times in 19 years)
Pedro Moreno, MD (7th year in a row)	Javed Suleman, MD (3rd year)

3 New York Times Magazine Super Doctors



Samin K. Sharma, MD (15th year in a row)	Atul Kukar, DO (3rd year in a row)
Annapoorna S. Kini, MD (13th year in a row)	Srinivas Duvvuri, MD (2nd year)
George Dangas, MD (6th year in a row)	

4 Samin K. Sharma, MD, Named Director of the Mount Sinai Cardiovascular Clinical Institute

Samin K. Sharma, MD, has been named Director of the Mount Sinai Cardiovascular Clinical Institute. In this new role within Mount Sinai Heart, Dr. Sharma will further enhance clinical care, operations, innovation, education, and clinical research.

Recent Appointments

SAMIN SHARMA, MD, NAMED DIRECTOR OF THE MOUNT SINAI CARDIOVASCULAR CLINICAL INSTITUTE

Dr. Samin K. Sharma has been named Director of the Mount Sinai Cardiovascular Clinical Institute. In this new role within Mount Sinai Heart, Dr. Sharma will further enhance clinical care, operations, innovation, education, and clinical research.



5 Annapoorna S. Kini, MD, STEMIcathAID app makes waves

The app, which shares critical patient information among the ED, transfer team, and Mount Sinai, has already made a huge impact and is saving lives.

Queens Ledger



App developed by Mount Sinai helps save woman's life

By Sebastian • March 20, 2022 • 5,533 Views • 0 Comments



An illustration on the cover of the Queens Ledger newspaper shows Annapoorna S. Kini, MD, MRCF, FACC, Director, Catheter Interventional Lab, and Zena and Michael A. Wiener Professor of Medicine, The Mount Sinai Hospital, New York, New York, with the STEMIcathAID app.

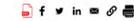
CathLabDigest

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TECHNOLOGY USE STEMI Team Communication at Mount Sinai Hospital Using the STEMIcathAID App

By Dr. Annapoorna S. Kini, MD, MRCF, FACC, Director, Catheter Interventional Lab, and Zena and Michael A. Wiener Professor of Medicine, The Mount Sinai Hospital, New York, New York

May 2022



What are the communication challenges faced by teams caring for acute myocardial infarction patients?



Figure 1: The STEMIcathAID app facilitates the communication and sharing of critical information. See [here](#) for more information on the app. See also our recent webinar, the app has been used with STEMI education myocardial infarction.

6 Prakash Krishnan, MD, led the 2nd annual NY Endovascular Summit and continuation of the Mount Sinai Endovascular Fellows Course

Dr. Krishnan was also honored by the Association of Indians in America.



7 Pedro Moreno, MD, named Director of the Cardiology Fellowship at Brooklyn Hospital Center, a Mount Sinai Affiliate



COMPREHENSIVE CARDIAC CARE

8 Roxana Mehran, MD, receives two Awards for supporting women in cardiology; and many others

Dr. Mehran was also listed in "2022 Most Cited Researchers—Top 1%", Clarivate Analytics (For the 8th year in a row).



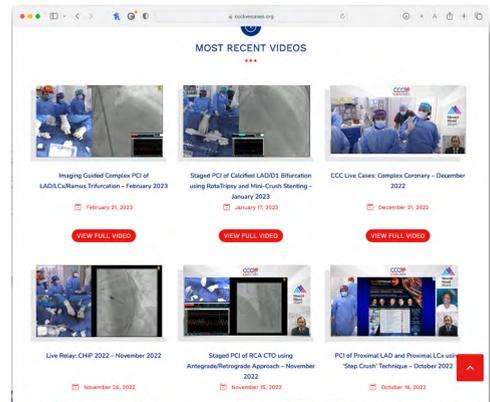
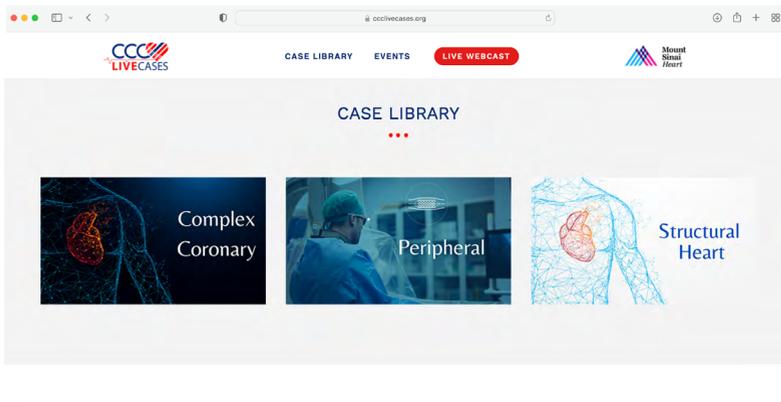
Mount Sinai's Roxana Mehran, MD, Receives "Women in Cardiology Mentoring Award" From American Heart Association

Honor recognizes her dedication to effectively mentoring female cardiologists

CCC Live Cases



www.ccclivecases.org



COMPLEX CORONARY

Every 3rd Tuesday of the month at 8 am EST

PERIPHERAL

Every 4th Wednesday of the month at 8 am EST

STRUCTURAL HEART

Every 2nd Tuesday of every other month at 9 am EST

**MORE THAN
2 Million
VIEWS**



WWW.CCCLIVECASES.ORG

An educational resource to view live complex coronary, peripheral, and structural heart cases.

Mount Sinai Heart Directory

Area	Telephone
MS Heart Director	212-241-7911
Adult Congenital Heart Disease Center	212-241-1382
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
Cardiac Catheterization Laboratory 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
MS 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

Contact Info

To make an appointment:

Phone: 212-241-0884

To refer a patient:

Phone: 212-241-5136

Scan the following
QR code to request an
appointment:



Publication of the *2022 Clinical Outcomes & Innovations Report* was made possible through generous gifts from the following people:

- Corrine Graber, in loving memory of her Mother, Theresa Kirwin
- Dr. Samin K. Sharma Family Foundation
- Eternal Heart Care Foundation
- Joseph Ficalora

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Marketing and Communications

“A team is not only a group of people who work together, a team is a group of people who trust and respect each other.”



Cardiac Catheterization Laboratory Mission:

To improve outcomes and safety of interventional patients by delivering clinical innovations, unrivaled research, and personalized clinical care as a team concept.

