NewYork-Presbyterian Cardiovascular Services
2019 Clinical and Scientific Innovations

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Welcome

Dear Colleague:

We are proud to bring you our 2019 Report on Clinical and Scientific Innovations in Cardiovascular Services. Our cardiologists, interventional cardiologists, and cardiac and vascular surgeons continue to advance treatment for heart disease through programs that are among the largest and most comprehensive in the country. The strength of our programs are rooted in the clinical, scientific, and educational excellence made possible by NewYork-Presbyterian’s affiliation with two renowned medical schools – Columbia University Vagelos College of Physicians and Surgeons and Weill Cornell Medicine.

Our physicians and surgeons are leaders and innovators in the field, working collaboratively to develop and refine minimally invasive techniques that ease recovery for patients while achieving greater survival with fewer complications. These include the ever-growing application of transcatheter interventions; the use of robotics in cardiac surgery; and new drug and device-based treatments for arrhythmias.

In 2019, we were pleased to welcome Dr. Nir Uriel as Director of Advanced Heart Failure, Cardiac Transplantation and Mechanical Circulatory Support Programs at NewYork-Presbyterian, and Professor of Medicine in the Division of Cardiology at Columbia University Vagelos College of Physicians and Surgeons and Adjunct Professor of Medicine in the Greenberg Division of Cardiology at Weill Cornell Medicine. An internationally recognized leader in heart failure, mechanical circulatory support, and heart transplantation, Dr. Uriel will oversee heart failure programs at NewYork-Presbyterian’s campuses in Manhattan, Queens, Brooklyn, and Westchester, with a goal to increase accessibility of care for those with advanced heart failure throughout the New York area.

We invite you to learn more about the work of our physicians and scientists in heart failure and transplant, structural heart disease, aortic disease, and vascular disease, including recent progress in transcatheter, endovascular, and surgical procedures. With a shared goal of improving the lives of patients, we are committed to extending the boundaries of what is possible in diagnosis, management, and treatment of cardiac and vascular disease.

Sincerely,

Dr. Augustine M.K. Choi

Dr. Lee Goldman

Dr. Steven J. Corwin

Steven J. Corwin, MD
President and Chief Executive Officer
NewYork-Presbyterian

Lee Goldman, MD
Dean of the Faculties of Health Sciences and Medicine and Chief Executive
Columbia University Irving Medical Center

Augustine M.K. Choi, MD
Stephen and Suzanne Weiss Dean
Weill Cornell Medicine
Measures of Distinction

Clinical Care

241
Physicians

17,887
Adult Patient Discharges

149
Dedicated Cardiovascular Beds

99
Cardiovascular ICU Beds

Graduate Medical Education

273
internal medicine residents who rotate through cardiology programs

16 residents
in cardiothoracic surgery residency programs

80 fellows
in fellowship programs that include:
• Adult Congenital Heart Disease
• Advanced Cardiovascular Imaging
• Advanced Heart Failure and Transplant Cardiology
• Cardiac Electrophysiology
• Cardiovascular Disease
• Complex and High Risk Coronary Intervention
• Endovascular Intervention
• Interventional Cardiology
• Structural Echocardiography
• Structural Heart Disease
• Thoracic Surgery
• Vascular Surgery

Research

$14.8 million
received from the National Institutes of Health and other organizations to support basic, translational, and clinical research

>325
clinical trials encompassing all areas of heart disease, with more than 3,900 patients enrolled

112
Clinicians and Research Scientists
Innovations at a Glance

➤ Originated the randomized multicenter ROMA trial aimed at evaluating the impact of the use of one internal thoracic artery versus two or more arterial grafts for coronary artery bypass graft

➤ Led a multicenter clinical trial finding that low-risk patients with severe aortic stenosis had a 46 percent lower risk of death, stroke, or rehospitalization when their aortic valve was replaced via TAVR versus open-heart surgery

➤ Developed a minimally invasive technique for transcarotid artery revascularization by directly accessing the carotid artery through a keyhole incision at the base of the neck

➤ Developing electromechanical wave imaging, a novel, non-invasive technology to better identify the origin of arrhythmias prior to cardiac ablation

➤ One of a handful of centers in the U. S. involved in a clinical trial to treat acute type A aortic dissections with the frozen elephant trunk graft technique

➤ Leading the international, multicenter RADIANCE-HTN SOLO and RADIANCE II trials to assess whether a device-based technique can reduce blood pressure

➤ Performed the first human case using the Conformal Left Atrial Appendage (LAA) Seal for LAA occlusion for the prevention of stroke in patients with atrial fibrillation

➤ Developed the AngioVac System, an endovascular suction device for filtering intravascular thrombi and emboli

➤ Offering the remedē® System, a newly FDA-approved phrenic nerve stimulation device for the treatment of central sleep apnea, a condition that can lead to heart failure and stroke

➤ Serving as sites for the NIH-sponsored CREST-2 trial assessing benefits of carotid stenting and endarterectomy versus intensive medical management to prevent stroke in patients with carotid stenosis who are asymptomatic
According to the American Heart Association, of the more than six million Americans living with heart failure, about 10 percent have advanced heart failure, a field that has grown dramatically in the last two years. “Unfortunately, more and more patients are suffering from heart failure, and not every patient is able to access the level of care they need,” says Nir Uriel, MD, an internationally recognized physician-scientist and the newly appointed Director of Advanced Heart Failure, Cardiac Transplantation and Mechanical Circulatory Support Programs at NewYork-Presbyterian. “There are options today that can help improve quality of life and increase longevity. Our goal is to reach as many of these patients as possible, regardless of where they live or their means, and provide them with the most advanced care so that they can enjoy life and have more time with their families and loved ones.”

In his new role, Dr. Uriel oversees heart failure programs at NewYork-Presbyterian’s campuses in Manhattan, Queens, Brooklyn, and Westchester, with a goal to increase accessibility of care for those with advanced heart failure throughout New York and the surrounding regions. The expanded program builds on an initiative begun in 2017 to standardize care for patients with heart failure across all the campuses of NewYork-Presbyterian. “We created a uniform pathway for the treatment of heart failure, which is applied at every NewYork-Presbyterian hospital,” says Paolo C. Colombo, MD. “Each hospital was actively engaged in reviewing the clinical dashboard to guide practice improvements. This culminated in implementation of guidelines and evidence-based standards for inpatient care, outpatient management of heart failure, and transitions of care.”

**Trials and Triumphs in Heart Transplantation**

“The heart transplant program at NewYork-Presbyterian is the biggest in the New York metropolitan area and one of the biggest in the country,” says Dr. Uriel. “This program has a long history with great success over many years performing heart transplantation and multi-organ transplants such as heart-kidney, heart-liver, and heart-lung transplantation.”

“2019 marks the 42nd year of our heart transplant program,” says Koji Takeda, MD, PhD. “In 2018, we performed 84 transplants bringing the total number of transplants at this center to more than 2,000. Data as of December 2019 show a one-year survival of 90 percent and three-year survival of 85 percent.”

NewYork-Presbyterian’s heart transplant specialists continue to pursue improvements in treatment protocols for high-risk transplant populations and define new approaches to increase heart transplantation as a treatment option for patients in end-stage heart failure. As one example, a new program for the use of hepatitis C viremic donors is increasing the availability of heart transplantation for those patients with longer waiting times on the list. A course of anti-viral therapy is administered at 12 weeks after transplant to cure the transmitted hepatitis C virus.

“To some extent we’re pursuing a personalized precision medicine approach around organ transplantation,” says Maryjane A. Farr, MD. “As we learn more about immunosuppressive therapies and ways in which we can monitor the immune system, we are able to give patients only what they need for immunosuppression and not more. We hope that being able to better refine the medications that one individual may need over another will translate into..."
longer-term survival and a better quality of life for a heart transplant recipient.”

“Here, in the NewYork-Presbyterian heart transplant program, we are trying to see how we can transplant patients who are considered to be too high risk for heart transplantation in other programs,” says Gabriel Sayer, MD. “Patients with a high level of antibodies who, historically, couldn’t receive heart transplantation, are being transplanted at NewYork-Presbyterian/Columbia University Irving Medical Center following novel desensitization protocols and the use of eculizumab, a new medication that allows us to overcome these immunological challenges. Furthermore, we were a pioneering center in transplanting HIV patients, and our research demonstrated that this group of patients do not carry a higher risk and should be eligible for advanced therapies.

A Landmark Change for LVADs

NewYork-Presbyterian offers one of the largest and most innovative ventricular assist device (LVAD) programs in the nation. The program led the original study to assess LVADs in patients with advanced heart failure who were not candidates for heart transplantation (the REMATCH study) and was a leader of the recent, seminal MOMENTUM 3 study that just ended this year. MOMENTUM 3 is the largest randomized trial in the history of mechanical circulatory support, assessing the use of the HeartMate 3™ LVAD in patients with advanced heart failure. The study was conducted in more than 60 centers across the United States and led to the FDA approval of the device. “MOMENTUM 3 was an important step forward for patients living with advanced heart failure,” notes Dr. Uriel, who served as the National Principal Investigator for the trial. “The study results will allow for wider use of the technology thanks to a significantly improved adverse event profile.”

“The NewYork-Presbyterian/Columbia surgeons and cardiologists were among the first nationwide to offer patients access to HeartMate 3 and enrolled the largest number of patients into the trial,” adds Yoshifumi Naka, MD, PhD. “The HeartMate 3 pump proved to be superior to previous LVADs as it eliminates the risk of pump thrombosis and dramatically reduces the risk of stroke.”

Addressing Clinical Challenges

Pulmonary hypertension is present in about one-third of patients with heart failure and complicates the management of this disease. “In many cases, right heart failure follows left heart failure, but management of difficult cases requires a special expertise and understanding of the interdependence of the right and the left ventricles,” says Evelyn M. Horn, MD, who has particular expertise in right heart failure. “The phenotype of heart failure has multiple etiologies, and not all heart failure behaves the same way. Because of the nuances and subtleties involved in advanced heart failure, identifying the optimal timing of therapeutic interventions is one of the challenges. It is essential to understand when therapies will or will not work, and when one has to move on to mechanical assist devices, or heart transplantation for heart failure and lung transplantation for pulmonary hypertension.”

The pulmonary hypertension program at NewYork-Presbyterian/ Columbia, led by Erika S. Berman Rosenzweig, MD, and the pulmonary hypertension program at NewYork-Presbyterian/ Weill Cornell, led by Dr. Horn, serve as two of the seven clinical centers across the country participating in the National Heart, Lung, and Blood Institute’s PVDOMICS (Redefining Pulmonary Hypertension through Pulmonary Vascular Disease Phenomics) program.

“The PVDOMICS study includes all spectrums of pulmonary hypertension, including patients with heart failure. We are nearing the target of our initial enrollment and will be arranging for follow-up on these patients,” says Dr. Horn. “The program will augment the current classification based on shared biological features of 1,500 participants that place them at increased risk of developing pulmonary hypertension.”

“By systemically characterizing pulmonary hypertension patients utilizing clinical, biochemical, imaging, and physiological and pathological assessments, combined with genomic and RNA technology, we can improve our mechanistic and pathobiological understanding of the

(continued on page 6)
pulmonary vascular disease process,” says Dr. Berman Rosenzweig. “The goal is to be able to better target the right patient for the right therapeutic intervention.”

In the contemporary era, Extracorporeal Membrane Oxygenation (ECMO) is a mandatory tool to take care of patients with heart failure and pulmonary hypertension. The Adult ECMO Program at NewYork-Presbyterian/Columbia is one of the largest, most experienced, and most innovative ECMO programs in the world and has once again been recognized by receiving the “Platinum Level ELSO Award for Excellence in Life Support” from the Extracorporeal Life Support Organization (ELSO). The prestigious platinum award is the highest distinction given by ELSO, only achieved by a select number of institutions worldwide. Platinum Level recognizes programs that display exceptional care in the delivery of ECMO support in patients with severe cardiac or pulmonary failure. “With our knowledge and experience, our program can provide the best care and the best outcomes to patients with heart failure and pulmonary hypertension,” says Dr. Takeda.

Dr. Takeda’s expertise intersects with all phases of heart failure care, including pulmonary thromboendarterectomy (PTE), a challenging and complex procedure to address chronic thromboembolic pulmonary hypertension. “This a chronic condition in which patients develop pulmonary hypertension that can become life-threatening. PTE has been shown to be the best treatment in extending a patient’s survival,” says Dr. Takeda, who leads one of the largest programs in the country for this highly specialized surgery. “When we remove the obstructing thromboembolic material, symptoms such as shortness of breath, edema, and fatigue dramatically improve. But it requires careful patient selection, a surgical skill set, and a high level of postoperative medical care and management.”

The team at the NewYork-Presbyterian/Weill Cornell campus is also committed to a multidisciplinary approach to patients with chronic thromboembolic pulmonary hypertension. Erin Iannacone, MD, believes the best short-term and long-term outcomes following complex PTE surgery come from a collaborative effort between the medical and surgical teams caring for these patients. “Without the expertise of both the heart failure and postoperative critical care teams, a perfectly executed operation is unlikely to succeed,” says Dr. Iannacone.

Having trained in PTE surgery at the busiest program in the world, Dr. Iannacone knows that a thorough preoperative evaluation by the heart failure team and meticulous postoperative care are the keys to success. “Patients can benefit tremendously from PTE surgery but a successful operation is just the beginning,” she says. “Ongoing communication between the heart failure and surgical teams reassures the patients and their families that they are receiving the most up-to-date, innovative therapies long after their operation is completed.”

Taking Care of Heart Failure Patients

“The expansion of the advanced heart failure entity across the NewYork-Presbyterian enterprise comes at a time when we are growing additional heart failure services, such as the Heart Failure with Preserved Ejection Fraction – HFpEF – program,” says Dr. Horn. “Our HFpEF program is the first and only subspecialty program in New York dedicated to this unique subtype of heart failure. Patients with HFpEF, also known as diastolic heart failure, develop heart failure symptoms such as fatigue and shortness of breath despite normal heart pump function.”

The HFpEF program, led by Parag Goyal, MD, MSc, combines treatment options with research in order to improve the care of this vulnerable population.

NewYork-Presbyterian/Columbia is the home for the biggest cardiac amyloidosis program in the tri-state area.
The program offers novel therapies to cardiac amyloidosis patients in different phases of the disease, including heart transplantation. “Currently, we are conducting four phase 3 studies of novel therapies for cardiac amyloid patients,” says Mathew Maurer, MD, who was the lead investigator and the first author on the recent *New England Journal of Medicine* publication demonstrating the role of tafamadis in treating TTR amyloid patients. “By phenotyping patients with cardiac amyloid we can come up with new therapies that will change those patients’ lives.”

The heart failure groups also have established a strong collaboration with the cancer centers at both NewYork-Presbyterian/Weill Cornell and NewYork-Presbyterian/Columbia. Novel protocols improve early identification and treatment of oncology patients who develop heart disease due to their cancer therapy. “This is a unique opportunity to help patients overcome the current cancer diagnosis that they are battling and protect them from future myocardial injury,” says Jayant Raikhelkar, MD.

**Growing Role of Remote Care**

An implanted hemodynamic monitoring system – CardioMEMS – is being used to remotely monitor and proactively adjust medications in patients with New York Heart Association Class III heart failure who have had a prior hospitalization. “Management is provided by a collaborative team of heart failure physicians and nurse practitioners,” notes Dr. Colombo. “In our first cohort of patients implanted, heart failure-related hospitalizations were reduced significantly.”

Dr. Horn and her team are pursuing a multi-tiered level of telemedicine efforts for remote monitoring of patients with chronic heart failure. The Community Tele-Paramedicine program uses video teleconferencing to deliver targeted, patient-centered, cost-effective acute care to patients’ homes via a bundle of innovative technologies. “Our team includes emergency physicians, heart failure cardiologists, a dedicated care manager, and full-time community paramedics,” notes Dr. Horn. “We have just completed a six-month pilot study with successful outcomes demonstrated with respect to improvement in medication reconciliation, adjustment of outpatient medication, appropriate referrals, care coordination, and decreased readmission in high-risk patients, as well as overall patient satisfaction.”

“There needs to be a true appreciation that heart failure is a life-threatening illness,” states Dr. Farr. “In stage three and certainly for class four heart failure, the one-year prognosis is worse than some of the worst cancers. Patients in heart failure, even with early-stage symptoms, fare much better when managed together with heart failure programs. In fact, the very advanced therapies such as heart pumps and transplant should be considered earlier in disease progression and may be the best strategy for better long-term survival.”

In summary, says Dr. Uriel, “Today, in NewYork-Presbyterian, we can offer heart failure therapies across a wide variety of conditions and stages of disease, from diagnosis, medical management, and monitoring to advanced heart failure options such as heart transplantation and LVAD support. We will be there for the patients in each stage of the disease and try to make sure they get the best chance to live a long life and enjoy a good quality of life.”

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**Nir Uriel, MD, Director of Heart Failure, Cardiac Transplantation and Mechanical Circulatory Support Programs at NewYork-Presbyterian**

**Gabriel Sayer, MD, Associate Director of Heart Failure, Cardiac Transplantation and Mechanical Circulatory Support Programs at NewYork-Presbyterian**

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**Intranasal Spray for Supraventricular Tachycardia**  
An intranasal medication spray for treating paroxysmal supraventricular tachycardia is currently being investigated at NewYork-Presbyterian/Weill Cornell Medical Center and sites throughout the country. “The NODE-301 and NODE-302 clinical studies are extensions of the NODE-1 efficacy study, which demonstrated an 87 percent effectiveness of the etripamil nasal spray in terminating spontaneous episodes of supraventricular tachycardia within a few minutes,” says James E. Ip, MD, Director, Cardiac Pacing and Implantable Devices. “Patients are now being trained to use the device and once they qualify, they can self-administer the medication during an episode of tachycardia.”

**Alternative to Biventricular Pacing**  
Individuals with congestive heart failure benefit from cardiac resynchronization therapy (CRT). However, according to Dr. Ip, approximately 5 to 10 percent of patients cannot be implanted with left ventricular leads due to their anatomy. “Their vessels are too small or are unable to be cannulated,” he says. “Sometimes the vessels are near the phrenic nerve, which we don’t want to stimulate or in areas that require too much energy to stimulate.”

In these cases, the only treatment option is open-heart surgery in which the lead is placed on the outside of the heart. Weill Cornell is participating in the multicenter SOLVE-CRT trial offering the WiSE™ CRT System, an investigational wireless cardiac stimulation system for the left ventricle. “This device consists of a small pellet that is about the size of a grain of rice placed on the inside of the left ventricle and stimulated by a subcutaneous implantable ultrasound transducer, which detects the stimulation from the right side of the heart,” says Dr. Ip. “It then sends an ultrasound beam to activate the pellet, which is sitting on the left side of the heart. It can provide resynchronization within a fraction of a second.”

**A New Path to Physiological Pacing**  
“Traditionally when we implant pacemakers, we place the wires in the right ventricle and attach it to the muscle, either at the apex or anywhere along the septum,” says Dr. Ip. “For some patients, this is not a natural way to stimulate the heart because the heart inherently has a conduction system that provides more coordinated, quicker stimulation. An alternative pacing method that has been gaining interest is placing the pacing wire in the middle of the heart to engage the heart’s natural electrical system. This can theoretically provide more physiologic and coordinated stimulation of the heart and can help some patients who require a lot of cardiac pacing.”

**A Pacemaker for the Lungs**  
Central sleep apnea is characterized by a lack of drive to breathe during sleep, resulting in periods of insufficient ventilation and compromised gas exchange. “Typically, as electrophysiologists, we are just involved in treating patients with electrical disease of the heart, but there is certainly overlap with patients who have heart failure or atrial fibrillation that causes dysregulation of the natural breathing rhythm,” says Dr. Ip, who is now offering these patients treatment with the remedē® System, a newly FDA-approved phrenic nerve stimulation device. “The procedure involves implantation of two wires; one that senses the rate of breathing and another that stimulates the phrenic nerve. The device only turns on when the patient is sleeping and lying down. When the breathing pattern starts to slow down or stop, it stimulates the phrenic nerve to create a breath for the patient.”
Under the leadership of Hasan Garan, MD, the Cardiac Electrophysiology Department at NewYork-Presbyterian/Columbia University Irving Medical Center is engaged in studies to better understand arrhythmias and their treatment. Cardiac electrophysiologist Angelo B. Biviano, MD, MPH, in collaboration with Columbia’s Adult Congenital Heart Center led by Marlon S. Rosenbaum, MD, has been pursuing studies involving patients with congenital heart disease and arrhythmias. “Patients with tetralogy of Fallot have a high prevalence of atrial tachyarrhythmia and often undergo ICD implantation at younger ages,” says Dr. Biviano. In a 20-year retrospective study of 40-plus patients with TOF, Columbia researchers found that a lower therapy cutoff rate for ventricular tachycardia was associated with increased risk of inappropriate shocks, the majority of which occurred in the presence of atrial arrhythmias. The authors advise that the risks of inappropriate shocks be considered when setting tachycardia therapy parameters in these patients.

In a study published in the April 5, 2019, issue of JACC Clinical Electrophysiology, Dr. Garan, Dr. Biviano, and their colleagues reported on the outcomes of 140 patients undergoing catheter ablation for atrial tachycardia. “We determined that catheter ablation in patients with adult congenital heart disease is effective in controlling arrhythmias,” notes Dr. Garan. “Specifically, acute procedural success was a predictor of freedom from recurrence, and the majority of patients achieved multiple arrhythmia-free years.”

Faculty also collaborated on a study looking at predictors and rates of recurrence of atrial arrhythmias following catheter ablation. Led by Matthew Lewis, MD, MPH, the study reviewed 124 patients treated with catheter ablations at Columbia over 10 years. The study did not find a significant difference in recurrence rates by gender, age, non-Fontan diagnosis, or need for transseptal puncture. However, BMI was a significant risk factor independent of Fontan status. These findings may help guide treatment decisions for persistent arrhythmias in the adult congenital heart disease population.

Elaine Y. Wan, MD, a cardiac electrophysiologist, is developing in collaboration with Elisa E. Konofagou, PhD, who directs the Ultrasound Elasticity Imaging Laboratory in the Biomedical Engineering Department at Columbia University, electromechanical wave imaging (EWI), a novel, non-invasive technology to image cardiac tissue. “This modality uses ultrasound to image the origin of arrhythmias, including atrial tachycardia, atrial flutter, premature ventricular complexes, and accessory pathways in Wolff-Parkinson-White syndrome,” says Dr. Wan. “The ultrasound helps identify sources of the arrhythmias, which could be driven from either side of the atria, the right ventricle, or the left ventricle. Localization of arrhythmias is critical for treatment planning prior to cardiac ablation. The 12-lead electrocardiogram [ECG] can be limited in specificity and subject to inter-observer variability. By using the ultrasound probe, we can take many more views of the heart, which we combine to generate a 3-D map of the electromechanical activation of heart rhythm.”

Dr. Wan and her colleagues first evaluated the procedure in 15 pediatric patients with 100 percent accuracy in predicting the location of the abnormal pathway. Preliminary studies presented at the late-breaking trials of the Heart Rhythm Society showed in a double-blinded study of 55 adult patients that the imaging technology was superior to the standard of care with ECG. EWI predicted 96 percent of arrhythmia locations as compared with 71 percent with ECG analyses. “We hope EWI may enable us to better predict procedural risks, reduce the amount of time it takes for the procedure, limit unnecessary radiation, and achieve a better outcome,” says Dr. Wan.
Structural Heart Disease
Emerging Therapies: TAVR and Beyond

“With the PARTNER 3 clinical trial demonstrating that transcatheter aortic valve replacement performs better than open-heart surgery in patients with severe aortic stenosis at low surgical risk, TAVR has been established as the dominant therapy for aortic stenosis,” says Martin B. Leon, MD, Director of the Center for Interventional Vascular Therapy at NewYork-Presbyterian/Columbia University Irving Medical Center, and Principal Investigator of the trial.

“With the great successes of TAVR, transcatheter therapies are emerging for other types of structural disease,” adds Susheel K. Kodali, MD, Director of the Structural Heart and Valve Center at Columbia. “These include asymptomatic aortic stenosis, bicuspid aortic valve disease, and aortic regurgitation, as well as disorders of the mitral and tricuspid valves. Columbia faculty are taking the lead investigating new, less-invasive approaches to address these conditions.”

EARLY TAVR “The achievements of TAVR encouraged us to think about providing therapy before the onset of significant symptoms,” says Dr. Leon. He and his colleagues are in the third year of EARLY TAVR, a randomized trial led by investigators at Columbia University comparing outcomes of watchful waiting to earlier treatment in aortic stenosis to help determine the optimal time to intervene.

Addressing Aortic Stenosis and Regurgitation The JenaValve is designed to treat symptomatic, severe aortic stenosis and aortic regurgitation using a single valve prosthesis. “Unlike other TAVR designs, this technology allows transcatheter replacement in a patient with pure aortic regurgitation,” says Dr. Leon. “Along with our colleagues at MedStar Washington Hospital Center, we led the initial U.S. clinical trial evaluating the use of JenaValve in high risk patients with either aortic stenosis or aortic regurgitation. Initial results have demonstrated excellent hemodynamics and superior paravalvular leakage results.”

Replacing the Mitral Valve “The mitral valve has proven a lot more challenging than initially thought,” notes Dr. Kodali. “We are involved in trials looking at feasibility of transcatheter replacement. The Medtronic Intrepid valve, currently being studied in the APOLLO trial, is a self-expanding stent with an integrated tissue valve designed to be inserted via a catheter. Currently the device is inserted from an incision in the chest wall from the apex.” Dr. Kodali and Dr. Vinayak Bapat are helping to lead the development of a transseptal delivery system that would allow transcatheter delivery of the Intrepid valve from the femoral vein with a fully percutaneous approach. It is anticipated that the transseptal version will be rolled into the main trial.

Devices for Heart Failure Two new therapies are being investigated by Columbia researchers as an intermediate solution between medical therapy and ventricular assist devices. “AccuCinch is a device consisting of a series of connected anchors placed percutaneously that can be cinched to help remodel the left ventricle in patients with heart failure and reduced ejection fraction,” explains Dr. Leon. “This device is now in early feasibility studies. The second study is a pivotal clinical trial for an interatrial shunt device for patients with heart failure and preserved ejection fraction. When you have heart failure, the pressures in the left side of the heart are elevated. We are now studying if the placement of a shunt between the left and the right atrium will help balance the pressure levels and reduce symptoms.”

Left Atrial Appendage Closure This procedure eliminates the need for long-term oral anticoagulation in patients with atrial fibrillation and is emerging as a strategy for stroke prevention. The Left Atrial Appendage Closure Team at Columbia is directed by Robert J. Sommer, MD, who recently performed the first human case using the Conformal Left Atrial Appendage (LAA) Seal. The case served to initiate a multicenter study investigating the effectiveness of LAA occlusion with the Conformal device for prevention of stroke in patients with AFib.
Technology-based advances are enabling cardiothoracic surgeons to help the sickest and the oldest patients with disease complexity involving multiple valves, multiple bypasses, and aortic emergencies. “Valve surgery is probably undergoing the greatest evolution, becoming more prevalent as patients are living longer,” says Leonard N. Girardi, MD, Cardiothoracic Surgeon-in-Chief, NewYork-Presbyterian/Weill Cornell Medical Center. “Traditionally, these procedures were handled strictly through open-heart surgery. Today, a significant portion of the valve operations are being done through the groin endovascularly – by surgeons or with our interventional cardiology colleagues. If the procedure cannot be accomplished through the groin, we move to the next step, robotics. And from there, we can then consider minimally invasive approaches before proceeding to open-heart surgery.”

Weill Cornell is one of a handful of centers in the U.S. involved in a clinical trial to treat acute type A aortic dissections with the frozen elephant trunk graft technique, an approach used in Europe, but not yet FDA approved here. “This is an interesting procedure where you treat the aorta beyond what you would normally manage surgically,” says Dr. Girardi. “Having a regular graft with a stent graft attached to the end of it is a unique concept that had not been previously done. Potentially we could eliminate the need for a second operation by treating more of the aorta that is diseased through a sternotomy and never have to go into the left chest to treat the second part of the aorta.”

Four-dimensional flow MRI is enhancing surgical repair of aneurysms where the valve is spared. “By interpreting the flow dynamics in the aorta, we can determine if we are providing optimal flow to the coronary arteries and minimizing stress on flow in the native aorta beyond the aneurysm repair to minimize complications such as dissections or aneurysm formation,” notes Dr. Girardi. “We can tell how much stress is on the leaflets of the valve that we just saved and whether we should tweak the technique to make the physics better for heart function and coronary blood flow.”

“My top priority is to provide safe and effective surgical treatments in the least invasive way possible. I treat patients who might benefit from a minimally invasive or a percutaneous approach to treat the heart valves,” says Stephanie L. Mick, MD, Director of Robotic and Minimally Invasive Cardiac Surgery at Weill Cornell.

Much of Dr. Mick’s research centers on the optimization of robotic mitral valve repair. Among her investigations while at Cleveland Clinic was a large study showing that del Nido cardioplegia, previously only used in children, was also safe in adults. “The benefit of del Nido cardioplegia is that it streamlines valve operations and makes them more efficient, without risk to the patient. We also employ other techniques, such as the use of neochords, to make robotic mitral valve repair as efficient and effective as possible.”
Endovascular Interventions
Lifesaving and Life-Enhancing Approaches to Care

“There are many patients with severe peripheral artery and venous disease who are never diagnosed, let alone treated,” says Ajay J. Kirtane, MD, Director, Cardiac Catheterization Laboratories at NewYork-Presbyterian/Columbia University Irving Medical Center. “One of the critical components of taking care of patients with vascular disease is to be comprehensive and to address the overall state of the patient.”

“CTEPH] and who are not candidates for surgery or who have already had surgery, we are able to offer balloon pulmonary angioplasty. We have refined the procedure with techniques used in advanced coronary lesions, such as chronic total occlusions of the coronary artery, to bring those to bear in the pulmonary vasculature. This is a somewhat unusual approach, but because of our advanced coronary expertise, we felt comfortable applying it to the pulmonary vasculature.”

Drs. Kirtane and Parikh also served as the National and Site Principal Investigators of the international, multicenter RADIANCE-HTN SOLO and RADIANCE II trials to assess whether the device-based approach of renal denervation can reduce blood pressure. This study is comparing medication titration for hypertension control following endovascular ultrasound renal denervation vs. a sham procedure. The RADIANCE-HTN SOLO results at six months, published in the May 28, 2019, issue of Circulation, demonstrated that in patients with combined systolic and diastolic hypertension, fewer medications were administered in the renal denervation group compared with a sham control, and the blood pressure-lowering effect of endovascular ultrasound renal denervation was maintained at six months.

“The results of the RADIANCE-HTN SOLO trial are unique in that they represent blinded randomized data demonstrating that ultrasound renal denervation may have the potential to serve as an important adjunct to medications to lower blood pressure,” says Dr. Kirtane. “If confirmed in the larger and ongoing RADIANCE II trial, this therapy would have the potential to help patients reach their blood pressure goals, particularly for those who have problems taking medicines or who prefer not to take medication.”

“Our Vascular Medicine and Intervention group within the Center for Interventional Vascular Therapy has participated in and led many of the pivotal clinical trials of medicated stents, drug-coated balloons, and other device technologies that are now widely available,” says Dr. Parikh. “In addition, we are also deeply involved in education within the field and offer a one-year dedicated advanced training fellowship in vascular medicine and intervention. Our center is only one of a handful of sites in the country that offers this type of comprehensive training program.”
Endovascular Interventions
Hybrid Heart Team: A Model of Collaboration

Close collaboration of interventional cardiologists and interventional radiologists with cardiac surgeons continues to play an invaluable role in the treatment of cardiovascular diseases. Catheter-based technologies along with the public’s enthusiasm for minimally invasive approaches have made the hybrid heart team concept an attractive approach for physicians and patients alike.

“We have a large aortic surgery program with a high volume of open surgery, but we have many patients who are best suited for endovascular interventions,” says Christopher Lau, MD, cardiothoracic surgeon at NewYork-Presbyterian/Weill Cornell Medical Center. “We often work with the interventional cardiologists or interventional radiologists who are experienced with imaging techniques, wire and catheter manipulation, and percutaneous access techniques. At any given time, we work with several teams to cover all the bases for what is necessary for successful endovascular aortic interventions. By having several experts with specific skill sets thinking about the treatment instead of just one person, it helps us provide the optimal treatment, which translates into less operative time, less anesthesia, and a quicker recovery for our patients.”

“We plan and perform the endovascular treatment of aneurysms and dissections together as a team, rather than as individuals,” says Luke K. Kim, MD, an interventional cardiologist at Weill Cornell. “We have created a heart team comprised of a cardiothoracic surgeon, an interventional cardiologist, an anesthesiologist, and an image-focused cardiologist to provide the best care tailored to different clinical scenarios.”

“Our collaborations began with transaortic valvular cases and have taken off,” continues Dr. Kim. “We have a large population with challenging connective tissue disorders, such as Marfan syndrome. These patients have poor outcomes if the procedures are done suboptimally. It’s been great working with Chris as he has experiences surgically that add immeasurably to my experiences with catheter-based procedures that we both appreciate and find useful.”

Outside of the OR, Dr. Lau and Weill Cornell interventional radiologists have pooled their expertise in the development of the AngioVac System, an endovascular suction device for removing large intravascular thrombi and emboli.

Throughout his career, David W. Trost, MD, former Director of Interventional Radiology at Weill Cornell, has witnessed a natural evolution in the endovascular world. He now often collaborates with Dr. Lau on thoracic aortic aneurysm repairs.

“When I started in the 1990s, our stent grafts were completely homemade,” he says. “We would sit and sew graft material and put metal stents inside of it. We would then have to have it sterilized and compress it down into a delivery system in the operating room. Today, we have advanced imaging, state-of-the-art equipment, refined techniques, and greater knowledge, which allow us to treat conditions that we could not begin to dream of treating in a minimally invasive manner 20 years ago.”

In reflecting on Weill Cornell’s heart team approach, Dr. Trost gives high marks not only to the surgeons and anesthesiologists, but also to excellent postoperative management. “Before Dr Lau, I performed the endovascular procedures with Dr. Leonard Girardi, Chairman of Cardiothoracic Surgery and a world expert in the surgical repair of aortic aneurysms,” says Dr. Trost. “Dr. Girardi and his team have a phenomenal post-procedure recovery system in the cardiac ICU. The operation is just the beginning of the treatment process. The care after the operation is just as important to ensure optimal outcomes.”
Safe closure of a percutaneous axillary artery access site involves (A) a 90 cm long femoral artery sheath intussuscepted into the end of the axillary artery sheath and advanced into the distal subclavian artery (B) advancing the safety wire from the femoral sheath across the axillary artery puncture site into the brachial artery (C) removal of axillary artery sheath leaving Glidewire in place (D) completion angiogram following removal of axillary artery Glidewire
Vascular Disease
Accelerating Progress in Aortic Disease Management

Virendra I. Patel, MD, MPH, Chief of Vascular Surgery and Co-Director of the Aortic Center at NewYork-Presbyterian/Columbia University Irving Medical Center, and his colleagues are advancing the endovascular management of acute aortic dissection. “With recent FDA approval for the use of a new endovascular stent, we now are able to manage acute type B dissections of the descending thoracic aorta in a novel, less invasive way that will greatly impact a patient’s quality of life and longevity,” says Dr. Patel. “The stent graft is delivered through an incision in the groin to reach the entry tear, where it expands to prevent the aorta from rupturing and make a new path for the blood to flow.”

“We have published extensively on the benefits of early intervention in the acute and subacute phase of acute type B aortic dissection,” continues Dr. Patel. “Even in uncomplicated type B dissections, there are clear benefits of aortic remodeling and reduction of late aortic events, specifically ruptures and thoracoabdominal aneurysms. Five-year aneurysm-related mortality is lower in patients who have early interventions for these dissections.”

In collaboration with cardiothoracic surgeon Hiroo Takayama, MD, PhD, Co-Director of the Aortic Center, Dr. Patel performs hybrid aortic arch reconstructions with the frozen elephant trunk technique. “The first device for a complete aortic arch endovascular replacement is now available in the United States, going into its second stage feasibility study,” says Dr. Patel. “Because of our collaborations and high volume, we will be the only center participating in this trial in New York City and one of only three centers on the East Coast. This is a completely minimally invasive replacement of the arch in patients with the appropriate anatomy.”

“Current devices used in treating the aortic arch when the ascending aorta is diseased can be a source of a new dissection or injury due to the large size of the stent,” explains Dr. Patel. “Generally, in these patients, we replace the ascending aorta and create the anatomy for the appropriate landing zone for the arch device so that it lands safely in the prior graft. What is interesting in terms of the hybrid perspective related to the new device is that it allows us to fully replace the aortic arch while limiting the risks associated with the subtotal or total arch replacements in patients with acute dissections and large ascending or aortic arch aneurysms. So, this new trial is going to be very exciting.”

Enrollment criteria include patients with an ascending or aortic arch aneurysm deemed too high risk for open surgery; patients with a previous median sternotomy, which would make the re-entry into the chest a bit more treacherous; and those who have an inadequate landing zone or prior graft replacement of the ascending aorta.

A Hand-Drawn Surgical Blueprint
In planning for a complex aortic surgery, Dr. Virendra Patel will draw detailed before and after sketches of the aorta to prepare him for where he may encounter problems. “Looking at the scans, I’ll plan where I think the safe sites are to clamp the aorta without showering debris, where I think the anatomy is going to be tricky, and what arteries I’m going to reattach versus keep together,” says Dr. Patel. “I do this for all complex aneurysms. I absolutely think it helps impact recovery. The faster you do the operation, the better you do your organ protection, and the better and quicker the recovery.”
“Our cardiothoracic research enterprise involves several different arms, including a robust basic science and translational laboratory for cardiovascular disease,” says Michael Argenziano, MD, Chief of Adult Cardiac Surgery at NewYork-Presbyterian/Columbia University Irving Medical Center, and Director of the Cardiothoracic Surgery Research Laboratory and Clinical Research Program. Dr. Argenziano also serves as Columbia’s Principal Investigator in the Cardiothoracic Surgical Trials Network (CSTN), which is supported by the National Heart, Lung, and Blood Institute and the National Institute of Neurologic Disorders and Stroke.

We have been a member of CSTN since 2006 and have participated in dozens of trials in cardiac surgery and served as co-authors of several articles published in The New England Journal of Medicine and other prestigious publications,” notes Dr. Argenziano. “Columbia is one of only three CSTN member sites in New York State. Current trials are focused on five- to 10-year-follow-up in outcomes of patients with severe or moderate ischemic mitral regurgitation who underwent mitral valve operations and evaluating the benefit of concurrent tricuspid valve repair during mitral surgery.”

Cardiovascular research at Columbia is also focused on the genetics of cardiovascular disease led by Giovanni Ferrari, PhD, Scientific Director of the Cardiothoracic Research Program, with a particular emphasis on heart valve and vascular cell physiology, cardiac biomechanics, and the brain-heart axis. For more than two decades an NIH T32 Training Grant in cardiovascular disease, currently in its fourth renewal, has been providing opportunities for physician-scientist trainees to become independent investigators in cardiovascular research. And a Clinical Research Core oversees both publicly funded and industry-sponsored clinical trials in areas that include cardiac surgery, cardiology, and immunology.

Mario F.L. Gaudino, MD, directs Translational and Clinical Research in the Department of Cardiothoracic Surgery at NewYork-Presbyterian/Weill Cornell Medical Center. Dr. Gaudino’s research is centered on a fundamental question in coronary artery bypass surgery: Is the use of two or more arterial grafts compared to a single arterial graft associated with improved clinical outcome? The answer is being sought in an international study launched by Dr. Gaudino nearly two years ago. The ROMA trial – Randomized comparison of the clinical Outcome of single versus Multiple Arterial grafts – enrolled its first patient in January 2018.

“Today, we have 1,500 patients all over the world toward our goal to enroll 4,300 patients, age 18 to 70, in some 50 international centers,” says Dr. Gaudino, Principal Investigator. “Patients are being randomized to receive a single arterial graft or multiple arterial grafts and followed for 10 years. In addition to looking at mortality outcomes, we are also going to look at reduction in myocardial infarction, stroke, and need for repeated revascularization. I cannot say if one group will do better than the other, but I’m very confident that this will be the trial that will provide the final answer to CABG, the most common cardiac surgery operation that impacts the lives of millions of patients. There is no doubt that in coronary artery bypass surgery at the moment, everyone is waiting for the results of ROMA.”
NewYork-Presbyterian is one of the nation’s most comprehensive, integrated academic healthcare systems, encompassing 10 hospital campuses across the Greater New York area, more than 200 primary and specialty care clinics and medical groups, and an array of telemedicine services.

A leader in medical education, NewYork-Presbyterian Hospital is the only academic medical center in the nation affiliated with two world-class medical schools, Weill Cornell Medicine and Columbia University Vagelos College of Physicians and Surgeons. This collaboration means patients have access to the country’s leading physicians, the full range of medical specialties, latest innovations in care, and research that is developing cures and saving lives. Ranked the #5 hospital in the nation and #1 in New York in U.S. News & World Report’s “Best Hospitals” survey, NewYork-Presbyterian Hospital is also recognized as among the best in the nation in every pediatric specialty evaluated in the U.S. News “Best Children’s Hospitals” survey. Founded nearly 250 years ago, NewYork-Presbyterian Hospital has a long legacy of medical breakthroughs and innovation, from the invention of the Pap test to the first successful pediatric heart transplant, to pioneering the groundbreaking heart valve replacement procedure called TAVR.

NewYork-Presbyterian’s 47,000 employees and affiliated physicians are dedicated to providing the highest quality, most compassionate care to New Yorkers and patients from across the country and around the world. NewYork-Presbyterian hospitals are not for profit and provide more than $1 billion in benefits every year to the community, including medical care, school-based health clinics, and support for more than 300 community programs and activities.

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