NewYork-Presbyterian Cardiac and Vascular Services

2016 OUTCOMES AND QUALITY REPORT
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For More Information or to Make a Referral cardiacoutcomes@nyp.org
Dear Colleague:

During the past year, NewYork-Presbyterian – in partnership with Columbia University Medical Center and Weill Cornell Medicine – continued to build on the strengths of its many clinical and scientific endeavors in cardiac and vascular services with the fundamental goal of improving outcomes for patients. Our physicians and surgeons are world-renowned leaders in their fields, and our programs are among the largest and most comprehensive in the country. Patients routinely come to NewYork-Presbyterian for treatment of the most complex heart diseases and disorders, confident that we can help, and we do. We are very fortunate to have a cohort of clinicians and investigators who work closely together in developing new medications, devices, surgical techniques, and minimally invasive approaches that are changing the landscape of care for heart and vascular disease.

NewYork-Presbyterian is proud to serve patients who seek out our expertise and experience in cardiac care from not only our metropolitan area, but who also travel from across the country and around the world.

In the following report, I invite you to learn about NewYork-Presbyterian’s significant role in advancing clinical and research innovations in the field.

Sincerely,

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

Columbia University Medical Center takes pride in partnering with NewYork-Presbyterian and Weill Cornell Medicine to advance care for patients with cardiovascular disease. Together, our cardiac programs currently rank No. 1 in New York City and No. 3 in the nation.

Our expert cardiologists and cardiac and vascular surgeons have been at the forefront of the major clinical trials that have led to advances in coronary angioplasty and stenting. For example, every drug-eluting stent now available in the United States was approved through trials conducted by Columbia interventional cardiologists. Columbia was the first center in the nation to perform coronary interventional procedures using “robotic PCI,” which places stents and opens blockages using a precision-guided robotic system.

Our doctors have performed more than 2,000 transcatheter aortic valve replacements through the groin instead of by major chest surgery — the nation’s highest volume — and almost half of the interventional cardiologists who perform the procedure have been trained by Columbia experts. We have the world’s largest heart failure and transplantation program and a national referral center for catheter ablations to treat heart arrhythmias.

For children with congenital heart disease, Columbia doctors developed surgical techniques now used throughout the world, including the pioneering use of 3-D printing to help guide surgeries in the smallest of infants.

Our progress is attributable, in large part, to the highly specialized skills and experience of our multidisciplinary cardiac and vascular teams. It is our great privilege to be part of a major clinical and academic endeavor that has such a depth and breadth of expertise in cardiovascular disease.

Sincerely,

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

“Columbia University Medical Center takes pride in partnering with NewYork-Presbyterian and Weill Cornell Medicine to advance care for patients with cardiovascular disease.”

Dr. Lee Goldman
Dear Colleague:

Weill Cornell Medicine’s partnerships with NewYork-Presbyterian and Columbia University Medical Center are central to the work we do and enable us to achieve the best possible outcomes for patients. Our powerful collaborations in clinical care, biomedical research, and education ensure that cardiac patients receive world-class treatment, backed by the latest findings and performed by the most highly trained specialists.

At Weill Cornell Medicine, our cardiologists and our cardiac and thoracic surgeons are leaders in their field. They are refining surgical techniques, pioneering minimally invasive approaches and robotic surgery, and developing novel strategies for prevention and diagnosis. Working with colleagues across disciplines and at our partner institutions, they are propelling research forward and enhancing our understanding of how cardiovascular disease develops and progresses. Patients in New York and around the country are benefitting from these advances, as well as from the training provided by our faculty to the next generation of physicians and surgeons.

Weill Cornell Medicine is especially proud of the survival and quality of life outcomes achieved by our cardiac care teams, working in conjunction with NewYork-Presbyterian and colleagues at Columbia. Together we are committed to reducing morbidity and mortality from cardiovascular disease and to developing innovative, personalized strategies to enhance the care of cardiac patients worldwide.

Sincerely,

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

“Our powerful collaborations in clinical care, biomedical research, and education ensure that cardiac patients receive world-class treatment.”

Dr. Augustine M.K. Choi
“The growth of our cardiac and vascular programs is closely linked to the development of NewYork-Presbyterian's integrated academic healthcare network. Over the last three years, our institution has doubled in size. Today, patients throughout the region can receive the highest quality of care in their own communities.”

Dr. Laura L. Forese
Executive Vice President and Chief Operating Officer
NewYork-Presbyterian
GEOGRAPHICAL REACH OF CARDIAC AND VASCULAR PROGRAMS – NORTHEAST

We are proud to serve a diverse local, regional, national, and international population. In 2015, NewYork-Presbyterian physicians saw more than 23,000 patients for cardiac and vascular care.

NewYork-Presbyterian is one of the nation’s most comprehensive healthcare delivery networks, focused on providing innovative and compassionate care to patients in the New York metropolitan area and around the globe. In collaboration with two renowned medical school partners, Columbia University College of Physicians and Surgeons and Weill Cornell Medicine, NewYork-Presbyterian is consistently recognized as a leader in medical education, groundbreaking research, and clinical innovation.

NewYork-Presbyterian has four major divisions:

NewYork-Presbyterian Hospital is ranked #1 in the New York metropolitan area by U.S. News and World Report and repeatedly named to the magazine’s Honor Roll of best hospitals in the nation.

NewYork-Presbyterian Regional Hospital Network is comprised of leading hospitals in and around New York and delivers high quality care to patients throughout the region.

NewYork-Presbyterian Physician Services connects medical experts with patients in their communities.

NewYork-Presbyterian Community and Population Health features the Hospital’s ambulatory care network sites, community care initiatives, and healthcare quality programs.

NewYork-Presbyterian is one of the largest healthcare providers in the U.S. Each year, nearly 29,000 NewYork-Presbyterian professionals deliver exceptional care to more than two million patients.

www.nyp.org
Cardiac and Vascular Services Leadership

Dr. Michael A. Borger

Dr. Richard M. Green

Dr. Darren B. Schneider

Dr. Yoshifumi Naka

Dr. Michael Argenziano

Dr. Arash Salemi
In our second annual *Outcomes and Quality Report*, we are pleased to continue to bring you highlights of our diverse cardiac and vascular programs. Here you will read about the innovative endeavors that our cardiologists, cardiac electrophysiologists, interventional cardiologists, and cardiovascular surgeons are pursuing to maximize the outcomes of even the most complex cases.

We also share metrics that clearly demonstrate that the integrated efforts of NewYork-Presbyterian physicians and surgeons are making important inroads in all facets of cardiac and vascular diseases, and most importantly, in the outcomes of patients who suffer with them.

Michael Argenziano, MD  
*Chief, Adult Cardiac Surgery*  
NewYork-Presbyterian/  
Columbia University Medical Center

Leonard N. Girardi, MD  
*Cardiothoracic Surgeon-in-Chief*  
NewYork-Presbyterian/  
Weill Cornell Medical Center

Emile A. Bacha, MD  
*Chief, Division of Cardiac, Thoracic, and Vascular Surgery*  
NewYork-Presbyterian/  
Columbia University Medical Center

Richard M. Green, MD  
*Associate Chief,*  
*Division of Cardiac, Thoracic, and Vascular Surgery*  
NewYork-Presbyterian/  
Columbia University Medical Center

Michael A. Borger, MD  
*Director, Aortic Surgery*  
*Director,*  
*Cardiovascular Institute*  
NewYork-Presbyterian/  
Columbia University Medical Center

Karl H. Krieger, MD  
*Vice Chairman, Department of Cardiothoracic Surgery*  
NewYork-Presbyterian/  
Weill Cornell Medical Center
Our accomplishments are rooted in the close collaborations among our specialists, who develop strategies for each patient’s care based on insights from a multidisciplinary perspective. This enables us to determine which approach — medical, interventional, or surgical or a combination thereof — is best suited for the patient. We have pushed the field forward by working together.

With a shared goal of improving the lives of patients, the faculty of NewYork-Presbyterian, Columbia University Medical Center, and Weill Cornell Medicine are committed to extending the boundaries of what is possible in diagnosis, management, and treatment of cardiac and vascular disease.

Martin B. Leon, MD  
Director, Center for 
Interventional Vascular Therapy  
NewYork-Presbyterian/ 
Columbia University Medical Center

Arash Salemi, MD  
Surgical Director, 
William Acquavella Heart Valve Center  
NewYork-Presbyterian/ 
Weill Cornell Medical Center

Bruce B. Lerman, MD  
Chief, Maurice R. and 
Corinne P. Greenberg 
Division of Cardiology  
NewYork-Presbyterian/ 
Weill Cornell Medical Center

Darren B. Schneider, MD  
Chief, Division of Vascular 
and Endovascular Surgery  
NewYork-Presbyterian/ 
Weill Cornell Medical Center

Yoshifumi Naka, MD, PhD  
Director, 
Cardiac Transplantation 
and Mechanical Circulatory Support Program  
NewYork-Presbyterian/ 
Columbia University Medical Center

Allan Schwartz, MD  
Chief, Division of Cardiology  
NewYork-Presbyterian/ 
Columbia University Medical Center

Craig R. Smith, MD  
Surgeon-in-Chief  
NewYork-Presbyterian/ 
Columbia University Medical Center

Dr. Bruce B. Lerman

Dr. Allan Schwartz

Dr. Martin B. Leon

Dr. Karl H. Krieger

Dr. Emile A. Bacha

Dr. Craig R. Smith

Dr. Leonard N. Girardi
From medical management to device development and new ways of applying interventional and surgical approaches, NewYork-Presbyterian is committed to elevating the fields of cardiac and vascular disease.
NewYork-Presbyterian cares for patients with some of the most complex ischemic heart disease who have very few treatment options. The Hospital’s mortality rate for patients with heart attack is 22% lower than the national average.

**Left Main Coronary Artery Disease** Our interventional cardiologists and cardiac surgeons were lead investigators for a landmark international study of 1,900 patients establishing that drug-eluting stents are as safe and effective as surgery for most patients with left main coronary artery disease (LMCAD) of low-to-intermediate complexity. Findings from the EXCEL (Evaluation of XIENCE versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization) trial were published online in 2016 in *The New England Journal of Medicine*.

**Bioabsorbable Stents** In July 2016, the FDA approved the first fully absorbable stent to treat coronary artery disease. The stent was studied in a clinical trial of more than 2,000 patients led by our physicians and conducted nationwide. The study compared the absorbable stent with a drug-eluting metallic stent and found them clinically comparable. The bioresorbable vascular scaffold system releases the drug everolimus to limit the growth of scar tissue and it gradually becomes integrated as part of the vessel wall in approximately three years.

Myocardial infarction caused by a stenosis of the right coronary artery
Left Ventricular Aneurysm Exclusion  Our physicians are participating in a major clinical trial evaluating the first minimally invasive catheter-based treatment for ischemic heart failure following a heart attack. The Parachute® ventricular partitioning device is used to partition damaged, non-functional heart muscle from the healthy, functional segment to decrease the overall volume of the left ventricle and as a result increase the power of the ventricular contraction. The hope is that the technique will lead to less readmission and translate to reduced mortality.

EXPERT MANAGEMENT OF HIGHER-RISK PATIENTS

Our physicians have particular expertise in managing Complex Higher-Risk and Indicated Patients (CHIP), including those with chronic total occlusions, patients with poor left ventricular function who require hemodynamic support in order to undergo procedures, as well as patients with complex coronary disease and other comorbid conditions, including renal insufficiency. In fact, we have one of the most robust chronic total occlusion programs in the country with several hundred cases treated each year.

Our physicians are facilitating widespread cognitive and technical expertise in these areas through the creation of a CHIP national interventional training program, which trains physicians around the country in these newer approaches, and with their recent position paper published in Circulation (August 2, 2016): “Treatment of Higher-Risk Patients with an Indication for Revascularization: Evolution within the Field of Contemporary Percutaneous Coronary Intervention.”

NewYork-Presbyterian’s angiographic success rate for stented lesions, excluding chronic total occlusions, is 99.7%.

(continued on page 10)
Emphasizing Cardiac Testing in Appropriate Patients  Our physicians also have reported on the underutilization of specific cardiac testing in high-risk populations, such as those with heart failure. They have found that the current emphasis on reducing the number of procedures and tests for healthier patients may have resulted in underutilization of care for sicker patients (such as those with congestive heart failure). Their analysis showed that patients hospitalized with heart failure are frequently not adequately tested and therefore may not be able to benefit from evidence-based therapies.

Use of Intravascular Imaging and Physiology  As part of the management advancing the care of patients with complex coronary artery disease, our physicians frequently employ cutting-edge technologies for intravascular imaging and physiology during the care of these patients. Several high-impact clinical trials in this area have been completed or are underway under the leadership of our physicians. As an example of the commitment to using these technologies to impact patient care, our physicians have pioneered an approach to revascularize patients with advanced kidney disease without the use of intravenous contrast through the use of intravascular ultrasound, optical coherence tomography, and pressure-guided assessments of lesion severity.

High-Risk Revascularization  Patients with coronary artery disease today are older and sicker, with more advanced disease and fewer treatment options due to comorbidities. Many patients who are referred to NewYork-Presbyterian are considered “high risk” because of advanced age, complex coronary disease, and/or previous heart surgery, multiple stenting, or other catheter interventions. While the number of bypass surgeries performed nationally has decreased dramatically, CABG is still the best overall operation for patients with diabetes, left main or triple vessel disease. We have one of the finest programs in the nation for high-risk coronary revascularization as well as its various iterations, including off-pump coronary bypass, and minimally invasive coronary bypass with and without robotic assistance.
Our expertise and experience in hybrid revascularization enables us to provide a combination of therapies to patients with complicated, extensive coronary artery disease. This may include, for example, off-pump or minimally invasive coronary bypass for certain vessels, and stents or other catheter-based techniques for other vessels. The approach is tailored to each patient based on their specific anatomy, allowing the benefits of the best surgical and interventional procedures now available.

Among 1,194 hospitals in the United States, NewYork-Presbyterian's mortality was better than the national average for CABG.

Bilateral Internal Mammary Arteries for CABG A nationally accepted measure of the quality and sophistication of a cardiac surgery program is the proportion of coronary bypass operations performed with internal mammary arteries (IMA), which have greater longevity than vein bypasses. While the use of one IMA is a standard expectation for CABG, the use of two IMAs – bilateral IMA – provides even better outcomes, but is much less common due to its technical complexity. In fact, while nationally only 6 percent of all coronary bypass operations are performed with bilateral IMA, at NewYork-Presbyterian bilateral IMA are used in approximately 70 percent of cases, placing our program among the top in the country. For those patients who may not qualify for bilateral mammary artery grafting, we offer radial artery grafts as an alternative. We have shown superior survival in patients in whom radial arteries were utilized instead of saphenous vein grafts.

Cardiogenic Shock Team Despite advances in the treatment of coronary artery disease and in the technology of mechanical circulatory support devices, patients with myocardial infarction complicated by cardiogenic shock still have mortality rates in the range of 40 to 50 percent. Collaboration between multiple specialties is the key to better outcomes for these patients. To this end, NewYork-Presbyterian has established a multidisciplinary Cardiogenic Shock Team representing cardiothoracic surgery, interventional cardiology, advanced heart failure, and critical care specialties with availability of mechanical circulatory support 24/7.
## Selected Clinical Trials

**ABSORB III Trial**  This prospective randomized, multicenter trial supports the U.S. premarket approval of the Absorb™ Bioresorbable Vascular Scaffold System.

**ABSORB IV Trial**  This trial continues to evaluate the safety and effectiveness as well as the potential short and long-term benefits of the Vascular Absorb™ and the Absorb GT1™ BVS System, as compared to the control stent XIENCE.

**IDEAS Trial: Innovative Discharge Education for Acute Coronary Syndrome and Stable Heart Disease Patients**  The purpose of this study is to assess the impact of patient-derived discharge interventions on quality of life, medication compliance, and readmission rates for STEMI, NSTEMI, and ACS patients who are discharged rapidly from the hospital. The study includes the opportunity for patients to review their own angiogram.

**ISCHEMIA: International Study of Comparative Health Effectiveness with Medical and Invasive Approaches**  This trial will determine the best management strategy for patients with at least moderate ischemia on stress imaging. Patients will be assigned to cardiac catheterization followed by revascularization plus optimal medical therapy (OMT) or to OMT, with cardiac catheterization and revascularization reserved for those who fail OMT.

**PARACHUTE IV: A Pivotal Trial of the Parachute Implant System**  This trial will evaluate the Parachute implant in approximately 560 patients with ischemic heart failure in up to 80 centers in the U.S. The event-driven primary endpoint includes all-cause mortality and hospitalization for worsening heart failure.

**SHIELD II: Supporting Patients Undergoing High-Risk PCI**  This study will evaluate the HeartMate PHP System, a temporary (<6 hours), high-flow percutaneous left ventricular support device system indicated for use during high-risk PCI performed in patients with severe coronary artery disease and depressed left ventricular ejection fraction.

## Selected Publications


NewYork-Presbyterian’s advanced heart failure programs offer a continuum of care for patients in all stages of heart failure – from medical management to ventricular support and heart transplantation. Our patients present with advanced cardiac disease with myriad causes and comorbidities. These include genetic abnormalities, diastolic heart failure, ischemic or hypertrophic cardiomyopathy, valvular disease, and heart attack.

At the core of these programs are multidisciplinary teams with highly specialized expertise in assessment and management of these complicated cases. Team members include specialists in gastroenterology, pulmonology, infectious disease, and cardiac anesthesia. These collaborations, coupled with meticulous perioperative, postoperative, and ongoing care, speak to our outstanding outcomes, including mortality rates lower than the national average.

**CardioMEMS** NewYork-Presbyterian is now incorporating CardioMEMS™ into its comprehensive management approach to the care of patients with heart failure. The cutting-edge tool allows continuous monitoring of a patient’s pulmonary pressure, facilitating early recognition of fluid accumulation and early intervention or medication adjustment before a patient becomes severely symptomatic necessitating an ED visit or hospital admission.

The CardioMEMS™ Heart Failure System is the first and only FDA-approved heart failure monitoring system proven to significantly reduce hospital admissions and improve quality of life in NYHA class III patients. The hemodynamic monitoring system is implanted into a distal branch of the descending pulmonary artery. The patient is instructed to transmit daily pressure readings – pressure trend information and individual pulmonary artery pressure waveforms – that are immediately available to physicians for review.

NewYork-Presbyterian has a 91% inpatient survival rate in patients undergoing care for advanced heart failure and a 30-day mortality rate 28% lower than the national average.
For more than 25 years, NewYork-Presbyterian has been a pioneer in the field of ventricular support for advanced heart failure management.

In 2015, our surgeons performed more than 150 left ventricular assist device (LVAD) procedures – one of the largest volumes nationwide – with survival rates that exceed the national average. They have played an integral role in the development of many groundbreaking devices, including several LVADS, such as HeartMate I and II, and most recently, NewYork-Presbyterian was one of the major sites for patient enrollment in the MOMENTUM 3 trial evaluating HeartMate 3.

MOMENTUM 3, which was the largest LVAD clinical study to date, tested this newest generation pump in more than 1,000 patients nationwide. The goal was to evaluate survival free from device replacement and debilitating stroke over a six-month period. The unique design of HeartMate 3 minimizes blood trauma and provides patients with an artificial pulse of 30 beats per minute.

The newer generation device features a centrifugal-flow durable left ventricular assist system that utilizes fully magnetically levitated technology engineered to lower adverse event rates, especially thrombosis. While HeartMate II is composed of an axial continuous-flow pump, HeartMate 3 uses a miniaturized centrifugal flow device and fewer moving parts, which help with surgical placement. At the end of the study’s six-month observation period, there were no significant differences in the rates of death or disabling stroke, and reoperation for pump malfunction or the need for urgent transplantation was less frequent in the centrifugal pump group.

HeartMate 3 (Courtesy of St. Jude Medical)
Patient Profiles
**INTERMACS**
June 23, 2006 - December 31, 2015

<table>
<thead>
<tr>
<th>Level Description</th>
<th>NewYork-Presbyterian</th>
<th>INTERMACS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1 Critical Cardiogenic Shock</td>
<td>11.7%</td>
<td>17.1%</td>
</tr>
<tr>
<td>Level 2 Progressive Decline</td>
<td>57.8%</td>
<td>37.2%</td>
</tr>
<tr>
<td>Level 3 Stable but Inotrope Dependent</td>
<td>25.0%</td>
<td>28.8%</td>
</tr>
<tr>
<td>Levels 4-7</td>
<td>5.5%</td>
<td>16.7%</td>
</tr>
</tbody>
</table>

*INTERMACS is the United States National Registry for patients receiving durable mechanical circulatory support device therapy to treat advanced heart failure.

Source: INTERMACS Quality Assurance Quarterly Report (Q4 2015)

Adverse Events*
**INTERMACS**
June 23, 2006 - December 31, 2015

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>NewYork-Presbyterian</th>
<th>INTERMACS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurological Dysfunction</td>
<td>3.10%</td>
<td>4.00%</td>
</tr>
<tr>
<td>Renal Dysfunction</td>
<td>1.90%</td>
<td>2.40%</td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>2.90%</td>
<td>3.90%</td>
</tr>
<tr>
<td>Pump/Related-Drive Line Infections (after the first 3 months)</td>
<td>0.75%</td>
<td>1.44%</td>
</tr>
<tr>
<td>Pump/Related-Drive Line Infections (during the first 3 months)</td>
<td>1.39%</td>
<td>1.43%</td>
</tr>
<tr>
<td>Bleeding</td>
<td>13.10%</td>
<td>13.60%</td>
</tr>
<tr>
<td>Rehospitalization</td>
<td>27.30%</td>
<td>38.00%</td>
</tr>
</tbody>
</table>

*Table includes overall counts and percentages for each type of adverse event reported at Hospital site and INTERMACS overall.

Source: INTERMACS Quality Assurance Quarterly Report (Q4 2015)
EXCELLENCE IN ADULT ECMO

In 2016, NewYork-Presbyterian’s Adult ECMO Program was designated a Platinum Center of Excellence in Life Support by the Extracorporeal Life Support Organization (ELSO). This is the first time Platinum Level status has ever been awarded. NewYork-Presbyterian is one of only three adult centers worldwide to achieve this designation.

The mission of NewYork-Presbyterian’s ECMO (Extracorporeal Membrane Oxygenation) program is to sustain life and provide the Hospital’s clinical team with the tools that support the most critical situations. The use of this evolving technology enables physicians to provide immediate cardiopulmonary support while resting the damaged native heart and lungs, improve perfusion and oxygenation of end organs, and allow ample time for diagnosis, treatment, and recovery from the primary injury or disease. At the same time, our clinicians strive to advance ECMO technology and novel applications to treat adult patients with life-threatening illness, while balancing ethical considerations and cost/benefit factors.

NewYork-Presbyterian has one of the largest medical ECMO programs in the world for adult respiratory failure. In 2016, the Extracorporeal Life Support Organization (ELSO) designated NewYork-Presbyterian’s Adult ECMO Program as a Platinum Center of Excellence in Life Support. This is the first time ELSO has ever awarded Platinum Level status, and NewYork-Presbyterian is one of only three adult centers worldwide to achieve this designation. Over the past five years there has been a significant increase in ECMO usage at NewYork-Presbyterian, due, in part, to referrals from other hospitals. Our ECMO team is available 24/7 for referrals and patient transfers.

**Innovative Hybrid Configurations**

Our clinicians have particular expertise in hybrid configurations that can provide differential support for various forms of cardiopulmonary failure. For example, for patients supported with venovenous ECMO who develop hemodynamic compromise, an arterial limb can be added (venovenous-arterial ECMO) to offer additional circulatory support. For patients on venoarterial ECMO who develop concomitant respiratory failure in the setting of some residual cardiac function, an oxygenated reinfusion limb can be added to the internal jugular vein (venoarterial-venous ECMO) to improve oxygen delivery to the cerebral and coronary circulation.

Venoarterial ECMO cannulation
CASE STUDY: PERIPHERAL VENOARTERIAL-ECMO AND LVAD

A 72-year-old man presented with severe dyspnea one week after an episode of excruciating arm pain for which he had not sought medical attention. An electrocardiogram showed evidence of an anterior myocardial infarction (MI), and coronary angiography revealed complete occlusion of the left anterior descending artery. Echocardiography revealed anterior wall akinesis, a left ventricular ejection fraction (LVEF) of 30%, and a large anterior ventricular septal rupture, a complication of MI that carries mortality as high as 80%. An intra-aortic balloon pump (IABP) was inserted, and the patient was transferred to NewYork-Presbyterian.

Given the size of the septal defect and the temporal proximity to the myocardial infarction, urgent surgical repair was deferred because of the anticipated friability of the septal tissue. However, despite IABP support, the patient developed worsening shock with hypotension and renal failure. Peripheral venoarterial extracorporeal membrane oxygenation (VA-ECMO) was implanted with cannulas in the right internal jugular vein and right axillary artery. This configuration provided robust hemodynamic support, while allowing the patient to participate in ambulatory rehabilitation and prevent the complications of being bedbound for weeks while awaiting surgery.

The patient was supported for two weeks with VA-ECMO, at which point the septal defect was deemed repairable, having completed the process of necrosis. With primary closure of the septal defect, further decline in LVEF was anticipated. Extensive discussions were held with the patient and his wife prior to surgery, and the patient consented to placement of a left ventricular assist device. Intraoperative transesophageal echocardiography revealed a large, 2 cm defect (shunt fraction 3.8). Through an anterior ventriculotomy the defect was found in the mid septum, surrounded by firm fibrotic tissue that allowed patch closure. A durable LVAD was inserted after the septal defect had been repaired, and the patient was transported to the recovery unit. He was extubated on postoperative day one. Transthoracic echocardiogram performed one week later showed no residual interventricular shunt and he was discharged to a rehabilitation facility. He is alive and well now living at home more than one year after his MI without experiencing any hospitalizations in the interim.
Founded over a quarter of a century ago, the heart transplant program at NewYork-Presbyterian has long been a premier center, with a transplant volume that is among the highest in the country. More than 2,300 adult and pediatric heart transplants have been performed here since 1988.

Heart Transplant

NewYork-Presbyterian has one of the largest and most active advanced therapy and heart transplant programs in the United States. Our surgeons and cardiologists have a distinguished history of advancing the standards of care and the survival rates of patients through innovative surgical techniques, applying basic research in immunosuppression to the clinical setting, and by inventing and perfecting life-sustaining cardiac assist devices that prolong life while waiting for organ availability or as a destination therapy for patients – including infants and small children – who are not eligible for transplantation.

Extended Donor Organs Heart transplant surgery remains limited to the most severe cases due, in part, to a shortage of donor hearts, which must pass through a stringent screening process. Moreover, there are many patients who – because of complicating health issues or age restrictions – are not eligible to be included on the transplant waiting list, yet are in need of a transplant. To address these issues, the heart transplant team at NewYork-Presbyterian expanded the usual criteria by which donor hearts are accepted, and these alternate waiting list strategies for heart transplantation are helping to maximize the use of extended donor organs. As a result, waiting times to transplantation are lower here than at other centers in the region, and the ability to transplant sooner translates into better post-transplant outcomes.

The heart transplant program has implemented extended criteria protocols for both organ donors and transplant recipients. Today, extended donor organs are utilized routinely and may be offered to patients over age 65, as well as to patients formerly considered too compromised to undergo transplantation. These extended criteria protocols are significantly widening the availability of organs and providing the option of transplantation with superior results to patients who would otherwise be denied transplant.
Selected Publications


Selected Clinical Trials

CIRT: Cardiovascular Inflammation Reduction Trial  This NIH trial is investigating whether low-dose methotrexate reduces heart attacks, strokes, or death in people with type 2 diabetes or metabolic syndrome who have had a heart attack or multiple coronary blockages.

COAPT Trial: Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional MR  This study will evaluate the safety and effectiveness of the MitraClip System for the treatment of moderate-to-severe or severe functional mitral regurgitation in symptomatic heart failure subjects not appropriate for mitral valve surgery.

MOMENTUM 3 Continued Access Protocol  This study will continue to evaluate the safety and clinical performance of the HeartMate 3 Left Ventricular Assist System for the treatment of advanced, refractory left ventricular heart failure.

PARACHUTE IV: Percutaneous Ventricular Restoration in Chronic Heart Failure  This randomized multicenter trial, which is designed to evaluate the Parachute implant, will enroll approximately 560 patients with ischemic heart failure in up to 80 centers in the U.S. The event-driven primary endpoint includes all-cause mortality and hospitalization for worsening heart failure. (Phase III)

TAVR UNLOAD: Transcatheter Aortic Valve Replacement for Advanced Heart Failure  The objective of this study is to determine the safety and efficacy of transcatheter aortic valve replacement via a transfemoral approach in heart failure patients with moderate aortic stenosis as compared with optimal heart failure therapy.
PULMONARY HYPERTENSION

PROGRESS IN PULMONARY HYPERTENSION

Our physicians offer rare expertise in the multidisciplinary management of the most complex multifactorial pulmonary hypertension across the spectrum of all ages. These include idiopathic and heritable pulmonary hypertension, and pulmonary hypertension related to diseases of the connective tissue, congenital heart and left heart disease, and lung, hematological, oncologic, and renal and hepatic diseases.

As one of the largest chronic thromboembolic pulmonary hypertension (CTEPH) centers in the country, NewYork-Presbyterian is home to the only regional multidisciplinary program for CTEPH, managing the most complex patients in partnership with one of the largest accredited Pulmonary Hypertension Centers in the world. By offering advanced medical, interventional, and surgical management of pulmonary hypertension and vascular disease, including catheter-directed fibrinolytic therapy, balloon pulmonary angioplasty (BPA), pulmonary embolectomy and pulmonary thromboendarterectomy (PTE), our center enables patients to access the entire spectrum of treatment options. Our chronic thromboembolic pulmonary hypertension and pulmonary thromboendarterectomy program is one of the largest in the country linked to an accredited Pulmonary Hypertension Center of Comprehensive Care, and we have performed more than 120 pulmonary thromboendarterectomy surgeries with excellent outcomes.

Pursuing Critical Research The pulmonary hypertension programs established at NewYork-Presbyterian more than 30 years ago have been at the forefront of clinical advances made possible by researchers at Columbia University Medical Center and Weill Cornell Medicine. They have long been leaders in the field of genetic discovery in cardiovascular disease and, notably, pulmonary arterial hypertension, having reported the very first mutation associated with inherited forms of pulmonary hypertension. More recently, researchers here have identified three novel genes for pulmonary hypertension using linkage analysis, association studies, comparative genomic hybridization, and whole exome/genome sequencing and RNA sequencing.

NewYork-Presbyterian’s Pulmonary Hypertension Centers are now accredited by the Pulmonary Hypertension Association as Pulmonary Hypertension Centers of Comprehensive Care.

Columbia and Weill Cornell faculty have also participated in the major clinical trials for the development of new drug treatments for pulmonary hypertension, and are currently pursuing studies of newer oral and inhaled therapies, including intravenous Flolan®. They are also serving as collaborators in the National Heart, Lung, and Blood Institute-sponsored Pulmonary Vascular Disease Phenomics (PVDOMICS) study. This study will assemble a cohort of patients across the World Health Organization groups 1 through 5 in order to redefine classifications of pulmonary hypertension based on pathobiologic mechanisms.

CTEPH Registry Columbia University Medical Center participates in the CTEPH Registry, a national registry to further our understanding of the natural history of incident cases of chronic thromboembolic pulmonary hypertension and interventions, including pulmonary thromboendarterectomy.

PAH Biobank NewYork-Presbyterian is an enrolling center for the National Biological Sample and Data Repository for Pulmonary Arterial Hypertension – also known as the PAH Biobank, a National Institutes of Health/National Heart, Lung, and Blood Institute-funded resource of biological samples, genetic data, and clinical data for the PAH research community. Its goal is to further PAH research by providing the largest cohort of WHO Group 1 PAH biological specimens and data for researchers to use in their studies.

Prevalence of Hypertension in Patients with Multiple Myeloma Weill Cornell researchers are undertaking a retrospective data analysis of patients with symptomatic untreated multiple myeloma currently undergoing evaluation of induction chemotherapies.
CASE STUDY: HEREDITARY PULMONARY ARTERIAL HYPERTENSION

A 52-year-old woman with hereditary pulmonary arterial hypertension (HPAH), initially diagnosed in 1998, was treated with subcutaneous remodulin, letairis, and revatio, with a previous history of atrial septostomy (2006 and 2007), and most recently metoprolol due to palpitations, PVCs and a hyperdynamic state. Her medical history also includes ulcerative colitis and pancreatic and ovarian cysts, and recent repeat genetic testing was positive for von Hippel Lindau disease without known association with HPAH. She underwent her routine monitoring, including right heart catheterization every two to three years, CPET and cardiac MRI monitoring of her right ventricle yearly (Figure 1), and follow-up of aneurysmal pulmonary artery dilatation and severe pulmonary insufficiency. Over the years, her catheterization revealed a mPAP 56mm Hg in 1996, 73 in 2007; she was an acute nonresponder; and most recently her RA 3 PA 65/24/40 PA sat 74% PCW 8 normal coronaries. Her most recent cardio-pulmonary stress test was a VO2 20.3 ml/kg/min (76%) R 0.91 VE/VCO2 35.2, and 6 minute walk test of 600 meters.

Thus, given acceptable hemodynamics, well-preserved functional status, and with a progressively increasing PA aneurysm, severe pulmonic insufficiency, and concern of RV outflow obstruction with RV septal bulge, she was referred for elective repair. Initial surgery included longitudinal opening of the pulmonary artery from just above the pulmonary valve out into the left hilum. The aneurysm was large enough that both the left upper lobe and intermediate branches of the pulmonary artery were actually within the mediastinal cavity. Extension of this incision showed aneurysmal dilatation out to the right upper lobe pulmonary artery as well. Trileaflet pulmonary valve was resected and replaced with a 23mm valve. A large portion of the pulmonary artery was then removed along the anterior surface of both right and left main pulmonary arteries, as well as the main pulmonary artery itself with initial thoughts of preservation of native PA compliance and responsiveness to vasodilators.

Intraoperative TEE did not show any RV outflow obstruction. However, later that evening she went into RV failure and was taken back to the OR for repair of pulmonary artery aneurysm with a 30mm woven Dacron graft and insertion of a right ventricular assist device. She progressed well over the next five days and her native ventricular function improved dramatically. Plans were for explantation of the RVAD but then she was more urgently taken back with diminished RVAD flows due to some acute outflow kinking; she tolerated explantation of her RVAD well.

Pathology of the explanted pulmonary artery showed medial degeneration and medial necrosis with fibrosis and lymphoplasmacytic inflammation of the outer portion of the adventitia. No intimal or medial inflammation is present (Figure 2).

She is now doing well, following an initial course of inpatient rehabilitation is less hyperdynamic, and is exercising regularly on a treadmill and doing well. Repeat clinical testing will be done in the context of the PVDOMICS. Extended genetic studies re the particular genetic abnormality of HPAH are being sought out and she will require routine monitoring for VHL disease.
CASE STUDY: CTEPH AND PREGNANCY

A 28-year-old pregnant woman with a history of multiple DVTs presented at 15 weeks gestation to a local emergency department with acute shortness of breath and mild hemoptysis. She had progressive dyspnea and cough over the next 4 weeks and presented again at 19 weeks gestation with dyspnea, cough, and hypoxia. Her oxygen saturation level was 92% on 4 L nasal cannula. A transthoracic echocardiogram demonstrated signs of severe pulmonary hypertension, and a chest CT with angiography had findings consistent with chronic thromboembolic pulmonary hypertension (CTEPH).

The patient was transferred to NewYork-Presbyterian for specialized management of her CTEPH and high-risk pregnancy. She underwent a ventilation/perfusion scan, which was also consistent with the diagnosis of CTEPH. Despite the known high risk of pregnancy and pulmonary hypertension, the patient decided to proceed with the pregnancy. A multidisciplinary team with experts from high risk obstetrics, pulmonary hypertension, extracorporeal membrane oxygenation, thoracic surgery, critical care, obstetric anesthesia, hematology, neonatology, and psychiatry managed the patient through the remainder of her pregnancy.

The patient was admitted to the ICU and treated with a number of advanced targeted pulmonary hypertension medications, including continuous intravenous epoprostenol. She developed severe hemoptysis and underwent urgent embolization of the bronchial artery collaterals. The patient had recurrent large-volume hemoptysis at 27 weeks gestation and underwent re-embolization. Her cough was suppressed, and she continued on targeted PAH therapies and heparin. There was serious concern about recurrence on the required anticoagulation for CTEPH, as well as many discussions about the optimal timing of delivery in light of maternal and fetal risks. The decision was made to deliver at 30 weeks gestation. General anesthesia and intubation were accomplished uneventfully for repeat cesarean section. The thoracic surgical team inserted guide wires into the right femoral artery and right femoral vein to facilitate emergent ECMO cannulation if needed.

Maternal intraoperative hemodynamic and respiratory status were unremarkable. The infant had some early respiratory difficulties, but soon improved and was discharged home with no residual medical problems. The patient was extubated in the OR and sent to the medical intensive care unit, where the expert ECMO teams are based.

Despite maximal medical therapy for pulmonary arterial hypertension, the patient remained very symptomatic and dependent on supplemental oxygen. A repeat right heart catheterization with selective pulmonary angiograms was performed. Hemodynamic characteristics confirmed severe PAH, and angiogram findings were consistent with bilateral chronic thromboembolic disease (Figure 1).

The pulmonary hypertension and thoracic surgery teams scheduled PTE when the patient’s condition was deemed stable at 6 weeks postpartum. Hemodynamics demonstrated normalization of the pulmonary arterial pressure in the immediate postoperative period without any operative complications (surgical specimen shown in Figure 2). The patient was discharged home on postoperative day 9 off all targeted PH medications and off oxygen. The patient remains asymptomatic and continues to do well with anticoagulation therapy. Her child remains in excellent health.

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Reference Article
Selected Clinical Trials

**BEAT: Beraprost-314d Added-on to Tyvaso®** This study will assess the efficacy and safety of BPS-314d-MR when added on to inhaled treprostinil (Tyvaso®) in patients with pulmonary arterial hypertension. (Phase III)

**LARIAT: Bardoxolone Methyl Evaluation for Pulmonary Hypertension** This study assesses bardoxolone methyl relative to placebo in patients with pulmonary hypertension to determine the recommended dose range, evaluate the change from baseline in a 6-minute walk distance, and determine the effect of bardoxolone methyl in pulmonary hypertension. (Phase II)

**Macitentan for Pulmonary Hypertension after LVAD Implantation** This study is evaluating the effect of macitentan 10 mg on pulmonary vascular resistance as compared to placebo in subjects with pulmonary hypertension after left ventricular assist device (LVAD) implantation. (Phase IV)

**PVDOMICS: Defining the Future Fingerprints of Pulmonary Vascular Disease** This prospective study is designed to lead to new understanding of patients with pulmonary hypertension and right heart dysfunction, based on molecular, clinical, hemodynamic, dynamic, and radiographic characteristics. Development of new classifications will be a product of association of these in-depth phenotypic descriptions with specific molecular mechanisms of pathogenesis. The protocol will be implemented to lead to identification of both sub-phenotypes of lung vascular disease and to biomarkers of disease that may be useful for early diagnosis or for assessment of interventions to prevent or treat this condition.

**Rituximab for Systemic Sclerosis-Associated Pulmonary Arterial Hypertension** This trial will determine if rituximab has a marked beneficial effect on clinical disease progression, with minimal toxicity, in patients with SSc-PAH when compared to placebo. (Phase II)

**TROPHY 1: Treatment of Pulmonary Hypertension – U.S. Study** The objective of this multicenter, nonrandomized study is to assess the safety, performance, and initial effectiveness of the TIVUS™ System when used for pulmonary artery denervation through subjective and objective change in clinical parameters and hemodynamic evaluation. (Not yet open for recruitment)

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Selected Publications


Patients with non-standard arrhythmias and anatomical anomalies, such as those with congenital heart disease, are routinely referred to NewYork-Presbyterian where the resources exist for providing treatment that requires sophisticated technology and specialized personnel experienced in the field of rhythm disorders.

OPTIMIZING ELECTROPHYSIOLOGY PROCEDURES

Weill Cornell Medicine researchers have been at the forefront of studying leadless pacemakers, which represent the newest device that can be offered to selected patients with constant atrial fibrillation with erratic rhythms. The miniaturized device, which is smaller than the size of a AAA battery, is placed with a steerable catheter directly into the right ventricle via the femoral vein. The wireless device reduces the risk of infection and removes the risk of wire compromise or damage.

Subcutaneous defibrillators are benefitting patients with heart abnormalities that would make it very difficult, if not impossible, to have the standard devices implanted surgically. Researchers at Columbia University Medical Center are major participants in the PRAETORIAN trial evaluating subcutaneous versus transvenous implantable cardioverter defibrillator therapy.

Columbia University Medical Center researchers are also investigating a number of other avenues to optimize various aspects of electrophysiology procedures. These include evaluating signal analysis to better perform ablation procedures, particularly in patients with atrial fibrillation and atrial flutter; refining MRI to tailor how images are collected for electrophysiology procedures; exploring how to improve data collection from electrograms, such as automating analysis for quicker accessibility and interpretation of large volumes of data; and working with Columbia’s Engineering Department to develop novel ways to image the heart to identify origins of arrhythmias using only echocardiograms.

ADVANCES IN ABLATION TECHNIQUES

Advances in technology continue to drive progress in the field of electrophysiology. Most recently this includes the ability to visualize what occurs in the heart electrically in addition to anatomically. This is particularly key in caring for adult congenital heart disease patients who often present with arrhythmia complications related to their extreme anatomical abnormalities. For example, patients with transposition of the great arteries and prior Mustard procedures have major differences in their cardiac anatomy and access to their atrial chambers for the treatment of atrial flutters. What
lesions did the patient have and what surgical procedures were performed to correct them? Were artificial grafts used in the chambers of the heart? This information needs to be taken into consideration when deciding how to reach the abnormal electrical circuits to be ablated. It may require trans-baffle punctures in patients who have undergone Mustard procedures. Treatment therefore involves considerable coordination for the ablation therapy, interfacing with adult congenital heart disease experts, cardiologists with expertise in imaging techniques, and often with the surgeons who performed the patient’s earlier procedures.

At NewYork-Presbyterian, patients benefit from this collaboration and care by physicians who have developed, studied, and continue to refine these procedures. They employ CT imaging and MRI to visualize the heart’s chambers prior to the procedure and intracardiac echocardiograms that provide real-time assessment and assist in navigation of the catheters. Advanced technology and skill and experience of practitioners have greatly decreased complications, increased success rates of these procedures, and importantly, broadened the audience of patients who can benefit.

**Mapping and Tracking Arrhythmias** Prior to recent technological advances, the complex and often transient nature of atrial fibrillation made mapping and tracking its spillover of electrical impulses impossible. NewYork-Presbyterian has one of the largest case volumes in the U.S. for ablation of ventricular tachycardia with remote navigation. The magnetic-based system allows for very precise and accurate movements of the catheters. With the use of a joystick, physicians can manipulate the magnets to change the orientation and direction of the catheters, enabling entry into crevices that are extraordinarily challenging to reach manually. The technology has enhanced treatments for certain types of unusual arrhythmias that until now were unsuccessful because of the lack of accessibility to certain areas of the heart.
In electroanatomic mapping, one magnet is located in the tip of the catheter and another is positioned beneath the cath lab table. This allows physicians to know at any time where the catheter is in three-dimensional space, enabling them to mark any area where there is a suspicion of electrical activity that could be helping to maintain or trigger the AF. Through a combination of touching the endocardial surface with the catheter and integrating this information with the intracardiac echo, as well as a pre-procedure CT scan, the left atrium is reconstructed in a three-dimensional form.

**Contact Force-Sensing (CF-sensing) Catheters** Our physicians are using the latest catheters that provide information on the force that is being placed on the heart during the ablation procedure to help determine whether the contact is suitable for delivering an effective ablation lesion. Newer ablation catheters allow physicians to assess whether adequate contact has been established with atrial tissue at the tip of the catheter. Prior to the availability of the CF-sensing catheter, there was a 20 to 30 percent recurrence rate following atrial fibrillation ablations. The force-sensing technology helps to overcome the challenge of drawing a complete line of block in a great many different areas in the atrium. A gap in the line of block can jeopardize the entire treatment. The CF-sensing catheter helps to ensure a complete lesion at each site of the ablation.

**Rotor Modulation Guided Procedures** In order for an arrhythmia to be sustained, there needs to be a substrate or perpetuator that allows atrial fibrillation to continue. This is particularly relevant for patients with persistent atrial fibrillation. The electrophysiological substrate is believed to be related to rapidly spinning rotors. These perpetuators are often located in the left atrium; however, in as many as 25 percent of patients, the right atrium may participate. A novel diagnostic catheter and mapping approach is enabling our physicians to pinpoint these rotors, which cannot be observed with the naked eye. Extensive computerized processing of electrical information highlights the coordinates of the rotors in a three-dimensional projection so that the ablation catheter can be directed toward those regions.
Weill Cornell Medicine researchers are principal investigators for the multicenter REAFFIRM study, which is evaluating rotor ablation followed by conventional ablation versus conventional ablation alone for the treatment of persistent atrial fibrillation. Weill Cornell is the only site in New York participating in this study.

**Ablations without Fluoroscopy** Our electrophysiologists are also pioneers in performing ablations on atrial fibrillation without fluoroscopy, reducing the time by 20 to 40 minutes for these complex procedures. Today, our physicians perform about 90 percent of ablation procedures for atrial fibrillation and 100 percent for atrial flutter without any fluoroscopy. They have accomplished this through novel integration of the existing technologies of intracardiac three-dimensional echocardiography with local 3-D electroanatomic mapping that has facilitated visualization of the heart and the ability to track the catheter in such a way that was previously not possible.

For ablations of ventricular tachycardia, which involves the most intensive fluoroscopic use – particularly in patients with structural heart disease – remote navigation is also used, but with less than five minutes of fluoroscopy. A multicenter clinical trial is now under development for the evaluation of a remote navigation system protocol for ablation of ventricular tachycardia due to structural heart disease.

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**Selected Clinical Trials**

**PRAETORIAN: Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator Therapy** This randomized controlled trial will outline the advantages and disadvantages of the subcutaneous implantable cardioverter-defibrillator compared to the transvenous ICD.

**REAFFIRM: Atrial Fibrillation Treatment with Focal Impulse and Rotor Modulation Guided Procedures** This study is designed to assess the safety and effectiveness of focal impulse and rotor modulation procedures followed by conventional ablation, including PVI versus a standard PVI procedure, for the treatment of persistent atrial fibrillation.

**SENSE Trial: Sensing Atrial High Rate Episodes with Implantable Cardioverter Defibrillators** The primary aim of this trial is to assess the efficacy of an implantable cardioverter-defibrillator lead with dedicated atrial sensing dipoles in detecting atrial high rate episodes.

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**Selected Publications**


COMPREHENSIVE CARE FOR ADULT CONGENITAL HEART DISEASE

It is expected that by the year 2020 more adults than children will need open-heart procedures to correct congenital heart defects. At NewYork-Presbyterian, cardiologists, interventional cardiologists, cardiac surgeons, and cardiac imaging specialists have come together to establish major programs in adult congenital heart disease. They continue to develop the burgeoning field to ensure that this growing adult population is treated by highly trained heart specialists who understand the unique physiological, anatomical, and clinical features of congenital heart disease at all ages.

NewYork-Presbyterian is one of the few programs in the country with the depth and breadth of expertise to address the multiple and complex anatomical abnormalities that can present in adult congenital heart disease.

NewYork-Presbyterian has a long history of addressing the complex needs of patients with adult congenital heart disease, having formed one of the first such programs in 1987. A collective effort among adult and pediatric specialists, our programs follow adult patients with a wide spectrum of congenital heart problems. These include cardiac defects often first discovered in adulthood, such as atrial septal defects and bicuspid aortic valve disease; complex birth anomalies that may have already required multiple surgeries in childhood, such as tetralogy of Fallot, transposition of the great arteries, coarctation of the aorta, and single ventricle anatomy or Fontan circulation, as well as a large group of congenital heart patients with pulmonary hypertension and Eisenmenger’s physiology.

Each year, cardiac surgeons with NewYork-Presbyterian’s Congenital Heart Center perform more than 700 cardiac operations, including some 25 heart transplants, 175 newborn heart repairs, and 100 adult congenital heart repairs.

(continued on page 30)
**CASE STUDY: ORTHOTOPIC BICAVAL HEART TRANSPLANT**

A 33-year-old male had a history of L-transposition of great arteries with ventricular septal defect, pulmonary atresia, mesocardia, and aneurysmal leftward ascending aorta. He had multiple cardiac surgeries: first a right classic Blalock-Taussig shunt in the neonatal period, then a modified Blalock-Taussig shunt at 1 year of age, then a left modified Blalock-Taussig shunt at 3 years of age, then a “physiologic repair” with VSD patch closure and 19mm homograft conduit between the left ventricle and the pulmonary arteries at 9 years of age, and finally the implantation of a pacemaker for heart block. He also had a history of atrial fibrillation and pulmonary embolism (on coumadin). He then developed a heart failure on his systemic right ventricle.

He was admitted to NewYork-Presbyterian and required femoral intra-aortic balloon pump and multiple ionotropes for hemodynamic support. The patient was listed for heart transplant. This heart transplant was high-risk given his clinical status, his anatomy (pulmonary artery on the right, aorta on the left, related to the L-transposition of great arteries), his multiple cardiac surgeries and sternotomies, and the presence of a highly calcified LV-PA homograft behind the sternum.

The patient underwent a complex orthotopic bicaval heart transplant with extraction of LV-PA conduit, patch plasty of the pulmonary artery confluence, aortoplasty to be able to connect the donor vessels (normal anatomy) and recipient vessels (ccTGA anatomy), and extraction of pacemaker generator and leads. Discharge echocardiography and right heart catheterization with endomyocardial biopsy showed a good biventricular function, with normal right heart pressures and biopsy showing ISHLT Grade 0 at the time of discharge.
COMPREHENSIVE CARE FOR ADULT CONGENITAL HEART DISEASE

Meeting Surgical Challenges With major successes in the surgical, medical, and critical care of infants with congenital heart disease, these patients are living into adulthood. However, as adults, many require reoperations. For example, adults who have had surgery for hypoplastic left heart syndrome as children face an uncertain future in terms of the right ventricle. Some of these patients can have very complex anatomy as adults. When they require further surgery, whether it is a corrective surgery, valve replacement, or a transplant, their physiology and anatomy are so complicated that they should be operated on by pediatric and congenital cardiac surgeons. NewYork-Presbyterian cardiac surgeons are very versatile in pediatric congenital heart surgery, enabling them to address these different types of patients as adults with their unique anatomy and physiology.

Congenital bicuspid disease is one condition seen frequently in adults because the valves replaced early on are prone to deterioration. Bicuspid valves create turbulent flow and because of that the wear on them is greater than with a normal tricuspid valve. These patients present with varying degrees of symptomatic aortic stenosis down the line. The vast majority are classified Sievers 1, which represents a partial raphé between two of the three native aortic valve cusps. Less common would be a complete fusion between two of the three cusps, and the least common form would be two cusps and no evidence of a third cusp whatsoever. Bicuspid valves generally fail earlier than their tricuspid counterparts, typically in middle-age.

In addition to correcting these challenging conditions with standard open-heart surgery, our surgeons are pursuing alternative technologies and techniques that include the Portico™ resheathable transcatheter aortic valve system. Weill Cornell Medicine is a major participant in the Portico™ clinical trial evaluating this transcatheter, self-expanding, nitinol-based valve. The valve, which is retrievable and repositionable, is used for patients with all forms of aortic stenosis, including those who have varying degrees of congenital malformations.

Selected Clinical Trials

ADVANCE ASO AMPLATZER™ Atrial Septal Occluder Post Market Surveillance This prospective, multicenter, case-cohort study aims to identify potential risk factors associated with the occurrence of erosion due to implantation of the AMPLATZER™ Septal Occluder.

Portico™: Resheathable Transcatheter Aortic Valve System U.S. IDE Trial This prospective, multicenter, randomized, controlled clinical study is designed to evaluate the safety and effectiveness of the SJM Portico Transcatheter Heart Valve and Delivery Systems (Portico) via transfemoral and alternative delivery methods.

TRACTOR: Ticagrelor Therapy for RefrACTORy Migraine This pilot study evaluates treatment of 40 patients with right to left shunt to assess the hypothesis that P2Y, G protein-coupled 12 (P2Y12) inhibition with Brilinta/ticagrelor (90 mg PO twice a day) reduces episodic and/or chronic migraine headache symptoms. (Phase IV)
**Rapid Growth of Interventional Procedures** While medical and surgical therapies for congenital heart disease have made significant strides in recent years, the field of interventional cardiology has, at the same time, experienced rapid growth. NewYork-Presbyterian’s interventional cardiologists have particular expertise in performing structural interventions for adults with uncorrected congenital heart defects, including patent foramen ovale (PFO) and atrial septal defects.

Patients considered for PFO closure are primarily those with cryptogenic stroke, ranging in age from their teens to early sixties. Every patient who is a candidate for PFO closure is assessed carefully with multiple diagnostic modalities to ensure that they do not have other cardiac or vascular defects that could give rise to stroke. They are evaluated for rhythm disorders, coagulation abnormalities, and other structural and vascular defects, to make sure that they are truly cryptogenic and that there are no contraindications to receiving a device.

Over the past 15 years, PFO closure has been performed using off-label devices approved for atrial septal defects. As of October 2016, the FDA has approved the AMPLATZER™ PFO Occluder as the first device in the U.S. officially indicated for PFO closure in cryptogenic stroke. Long-term data from the pivotal RESPECT trial showed a 45 percent relative risk reduction of recurrent ischemic stroke with device closure compared to medical therapy alone.

NewYork-Presbyterian’s interventional cardiologists have particular expertise in performing structural interventions for adults with uncorrected congenital heart defects, including patent foramen ovale and atrial septal defects.

**Selected Publications**


NewYork-Presbyterian’s hypertrophic cardiomyopathy (HCM) program manages patients with medications; a personalized program of exercise, diet, and nutrition; and interventions ranging from implantable cardioverter defibrillators to septal ablation or surgical myectomy. In the rare situation when a patient progresses to end-stage HCM, we are able to offer heart transplantation.

**Innovations in Surgical Approaches** Septal myectomy has been considered the gold standard for the treatment of severe, medically refractory symptoms resulting from left ventricular outflow tract obstruction. The classic surgical approach is the Morrow procedure, which involves gaining access to the ventricular septum by way of an aortotomy across the aortic valve. Limitations of this procedure are a midline sternotomy and a prolonged postoperative recovery.

Cardiothoracic surgeons at NewYork-Presbyterian/Weill Cornell have recently performed robot-assisted septal myectomy for HCM. This minimally invasive approach, rather than going through the aortic valve, takes a more direct path by entering from the right chest and going through the mitral valve to resect the septum. While there is not yet enough evidence to confirm that outcomes from the robotic approach are better than the Morrow procedure, our surgeons have reported excellent results to date.

**Stem Cell Research** Columbia researchers are utilizing a form of personalized stem cells that can be derived from a patient’s skin sample in order to develop human cardiomyocyte models of genetic heart disease, including HCM. While researchers know a good deal about the genes that are defective in HCM patients, there is little known about the downstream events that lead to hypertrophy of the heart muscle and the predisposition for sudden cardiac death. Skin samples taken from patients with HCM will permit the researchers to directly study patients’ heart cells in the laboratory. These studies may lead to new insights in the pathogenesis of HCM at the cellular and molecular level, potentially resulting in novel treatment for this debilitating disease.

**Novel Markers of Prognosis** Weill Cornell Medicine researchers are seeking to develop a predictive model of cardiovascular outcomes in HCM by using exploratory data mining methods to identify demographic, clinical, and novel cardiovascular magnetic resonance imaging, genetic, and biomarker variables associated with the outcomes. They are also developing a score from the predictive model that can be used to assess risk given a patient’s combination of risk factors, thus establishing the evidence base to develop a clinical trial designed to reduce morbidity and mortality in HCM.

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**Selected Publications**

NewYork-Presbyterian physicians are skilled in developing treatment strategies for cardiovascular toxicities associated with cancer therapies and also provide comprehensive care for patients with existing cardiovascular issues who have been newly diagnosed with cancer.

NewYork-Presbyterian’s program in cardio-oncology brings together experts in clinical cardiology, clinical oncology, cardiovascular imaging, cardiac surgery, and cardiac pathology. This broad expertise and experience is enhanced by access to the most advanced medical therapies and cutting-edge surgical technologies currently available.

Our cardio-oncology program provides care for patients who may experience cardiac side effects from traditional cancer therapies. Many of the commonly used new biologic agents have known cardiotoxic effects. Our physicians are skilled in developing treatment strategies for cardiovascular toxicities associated with cancer therapies. We also provide comprehensive care for patients with existing cardiovascular issues who have been newly diagnosed with cancer, working closely with the oncology team to identify chemotherapy agents that are safer for the heart. A major goal of the cardio-oncology program is to enable patients to remain on chemotherapy while minimizing cardiac damage.

NewYork-Presbyterian’s cardio-oncology program provides:

- Inpatient and outpatient consultations for patients with cancer
- Adult cancer survivors clinic
- Childhood cancer survivors clinic

Researchers at Columbia University Medical Center and Weill Cornell Medicine are focused on identifying mechanisms for cancer-related cardiac disease and improving cardiovascular outcomes in cancer patients.

**Cardiac Tumor Program** Cardiac tumors are a rare but serious condition that require a specialized center to achieve optimal patient outcomes. NewYork-Presbyterian’s program is one of only a few such programs in the region dedicated to caring for patients with a cardiac mass. Patients with tumors unresponsive to chemotherapy or radiation therapy are frequently referred to our program for care. There are two broad categories of patients who present with cardiac tumors: those who have primary cardiac tumors and those who have other tumors within the chest that invade the heart or great vessels. Our cardiothoracic surgeons have particular expertise in performing great vessel resection and reconstruction.

Our patients also benefit from access to the most advanced medical therapies and surgical technologies, as well as the latest oncology clinical trials for primary tumors or metastatic disease of the heart.

Lipoma in a left cardiac ventricle
VALVE DISEASE

NewYork-Presbyterian has established leading programs in the treatment of valve disease through multidisciplinary approaches that include surgical, interventional, and hybrid options. Columbia University Medical Center and Weill Cornell Medicine clinicians across cardiovascular specialties are at the vanguard of landmark clinical trials in the development, evaluation, and refinement of novel, less-invasive techniques for repairing and replacing damaged aortic, mitral, and tricuspid valves.

NewYork-Presbyterian physicians have performed more than 2,000 TAVR procedures since 2005. Our TAVR program is now among the top volume centers in the United States, with over 550 cases in 2015, and 70% of our patients are discharged in two days or less.

TRANSFORMATIVE AORTIC VALVE PROCEDURES

Aortic stenosis is a life-threatening condition that is present in more than 3 percent of the population, and the average age at presentation is 75 – a time when comorbidities often prevent patients from tolerating surgical therapies. Therefore, much of the focus on treatment of aortic valve disease and aortic stenosis has moved toward minimally invasive treatment, as well as expanding indications for any patients at high risk for surgery who may benefit from less-invasive approaches in which the paramount advantage is quick recovery.

Surgical valve replacement continues to be an important option for patients. These include patients with aortic stenosis, especially for younger patients, those with bicuspid aortic valves, and those requiring concomitant cardiac procedures. Determining which of several surgical approaches, including minimally invasive incisions, as well as the type of prosthetic heart valve to be implanted – mechanical or biologic – is facilitated by discussions among the heart team (cardiologists and surgeons) weighing the pros and cons of each approach. These include tradeoffs between the superior longevity of mechanical valves and the avoidance of lifelong blood thinners with biologic valves.
Valve Procedures

Procedures by Approach 2015

In-Hospital Mortality Rate 2015

Surgical Site Infection Rate 2011 - 2015

Aortic Valve Surgery

Aortic Valve Open Procedures Volume 2011 - 2015

In-Hospital Mortality Rate 2015

Isolated Aortic Valve Complications Rate 2015

*Expected mortality was determined using Vizient risk-adjustment methodology.
Source: Vizient Clinical Data Base/Resource Manager™ used by permission of Vizient. All rights reserved.
The TAVR Revolution  Over the past decade, transcatheter aortic valve replacement (TAVR) has undergone a tremendous evolution led by Columbia University Medical Center researchers in surgery and interventional cardiology. This started in 2007 with the pioneering work of the PARTNER 1 trial, which established TAVR as the standard of care for inoperable patients and as an alternative to surgery in high-risk patients. The success of this trial set the stage for PARTNER 2, also led by Columbia physicians, which focused on healthier patients in their 70s and 80s at intermediate risk for surgery. These studies resulted in FDA approval of TAVR for intermediate risk patients in 2016, as well as approval of a third generation transcatheter heart valve, the Edwards SAPIEN 3 prosthesis. These major achievements have resulted in a paradigm shift in the treatment of aortic stenosis. Today, TAVR has become an important component of patient discussions, and our interventionalists and surgeons speak with patients together to present all options in an open and unbiased manner.
The newer generation TAVR devices are much smaller. The procedures can be performed while the patient is awake. The rates of major vascular and bleeding complications are much lower. And while the longevity of the valve replacement is still under study, patients often prefer this technology because the hospital stay is only one to two days and recovery is much quicker than with open surgery. With over a 10-year history of experience in TAVR – the longest in the nation – Columbia researchers have now begun to study the longevity of valve replacement in patients who have had the procedure.

**PARTNER 3 for Low-Risk Patients** The success of the PARTNER 1 and 2 trials in higher-risk patients laid the groundwork for the current PARTNER 3 multicenter study, which will compare TAVR using the SAPIEN 3 balloon-expandable platform with surgical valve replacement in patients with symptomatic, severe aortic stenosis who are at low operative risk. Columbia serves as a principal investigator for the trial, which will begin to enroll approximately 1,200 patients across 50 sites. The subjects will be age 65 or older with a Society of Thoracic Surgeons risk score of less than 4 percent. The noninferiority trial has a primary endpoint comprising a one-year composite of death, stroke, or rehospitalization.

**Embolic Prevention During TAVR** About three to six percent of TAVR patients experience a stroke caused by embolic debris that becomes dislodged when the valve is replaced. Columbia researchers served as lead authors of an international study demonstrating that transcatheter cerebral embolic protection (TCEP) is safe, provides effective capture of embolic debris, and does not change neurocognitive function for TAVR patients. The SENTINEL trial enrolled 363 patients at 19 hospitals and is currently the largest randomized trial to examine the safety and efficacy of using neuroprotection during TAVR.
MULTIPLE OPTIONS FOR MITRAL VALVE DISEASE

As with many areas of cardiac disease, the state-of-the-art treatment of mitral valve disease today is multidisciplinary and involves medical therapies, surgical treatments, and transcatheter procedures. NewYork-Presbyterian’s mitral valve centers offer patients a range of treatment options not available just a few years ago. They continue to shift the surgical approach from replacement to repair and from open surgery to minimal access methods – including the less invasive mini-thoracotomy and robotic procedures – with great success. This is due in large part to a high volume of isolated mitral valve procedures performed by our surgeons. With increasing evidence that mitral valve repair has superior outcomes to replacement, the surgical treatment of mitral valve disease, particularly for mitral valve prolapse, is becoming more of a specialty operation best performed at high-volume academic medical centers.

Minimally Invasive Mitral Valve Surgery  Surgeons at NewYork-Presbyterian have been performing minimally invasive mitral valve surgery since 1998, and participated in the first clinical trials of robotic mitral valve repair over 15 years ago. The most common minimally invasive approach utilized by our surgeons is a right mini-thoracotomy, which utilizes a three to four inch incision between the ribs without cutting the breastbone, and allows mitral valve repair or replacement, as well as associated procedures such as tricuspid valve repair, atrial septal defect repair, and the Maze procedure for atrial fibrillation. To date, our surgeons have performed over 1,500 mitral valve operations via this minimally invasive approach and have taught this technique to hundreds of surgeons from all over the world.

NewYork-Presbyterian is one of the nation’s leading centers for mitral valve repair, which is much more difficult and challenging than mitral valve replacement, but provides a better, more durable solution for most patients.

Mitral Valve Surgery

Mitral Valve Open Surgery Volume 2011 - 2015

<table>
<thead>
<tr>
<th>Year</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
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<tbody>
<tr>
<td>Value</td>
<td>600</td>
<td>600</td>
<td>600</td>
<td>600</td>
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</tbody>
</table>

Source: NewYork-Presbyterian

In-Hospital Mortality Rate 2011 - 2015

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Observed</th>
<th>Expected*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitral Valve Repair</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Isolated Mitral Valve**</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Mitral Valve Repair + CABG</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Postoperative Stroke 1.7%
Renal Failure - New Onset Dialysis 1.3%
30 Days Readmission - Unplanned 7.6%
Postoperative Infection 0.9%

Source: Vizient Clinical Data Base/Resource Manager™ used by permission of Vizient. All rights reserved.

*Expected mortality was determined using Vizient risk adjustment methodology.
**Isolated mitral valve includes both mitral valve repair and replacement.
The Evolving Role of Robotics  The Hospital’s cardiac robotic surgery program, one of the few in the country, continues to evolve with a surgical team led by a cardiac surgeon with more than 15 years of experience in performing, evaluating, and refining a wide range of totally robotic cardiac surgical procedures. The program incorporates the newest iteration of robotics technology – da Vinci Xi® – for mitral valve reconstructions. While the earlier versions of the da Vinci robot involved a fairly large incision, the newest version has eight-millimeter ports. The da Vinci Xi surgical system employs instruments that are as dexterous as a surgeon’s hands, but considerably smaller, and a 3-D camera that provides vividly clear visuals. The minimally invasive approach performed through small incisions on the right side of the chest produces shorter hospitalizations of two to three days, less morbidity postoperatively, and less pain and suffering. Considered the least invasive approach of the mitral valve procedures, robotic surgery is typically found to be most beneficial in distant, small cavities or contained areas such as the left atrium where the mitral valve sits. The robot really excels in these situations, making it possible to take the camera into that small space and have the same degree of freedom as if the surgeon’s hands were physically in that space.

CASE STUDY: ROBOTIC ENDOSCOPIC SURGERY

A 45-year-old man had increasing shortness of breath. He went to his doctor who heard a murmur and sent him to a cardiologist. An echocardiogram showed severe mitral regurgitation. At first, this cardiologist recommended a surgeon who would do the surgery in the traditional way through the sternum (sternotomy). But the patient decided to search the internet and found that there was a good alternative: totally endoscopic robotic mitral valve repair available at NewYork-Presbyterian. His cardiologist encouraged him to explore all options. After a consultation in the office, the patient proceeded with robotic endoscopic surgery. The procedure went well and was performed with only tiny incisions. The valve was repaired successfully and the patient went home three days after surgery. He returned to work in three weeks, much earlier than would be expected after sternotomy.

This patient’s case highlights many important issues. For one, surgery in general is becoming much less invasive because patients value that and there are now ways to maintain and even improve on quality outcomes. The robotic surgical system makes it possible to do mitral valve repair through incredibly tiny incisions, as was done with this patient.

The procedure involves placing four pencil sized (8mm) ports and one thumb-sized port (15mm) in the right chest. A completely catheter-based system is used to go on the heart-lung machine and stop the heart. NewYork-Presbyterian has one of the few programs in the country to perform these procedures through such small incisions.
**New Technology for Mitral Regurgitation**

Patients with significant symptomatic degenerative mitral regurgitation who are not candidates for surgery are benefitting from a new catheter-based treatment called MitraClip, patented by physicians at NewYork-Presbyterian. The very low-risk procedure creates a tissue bridge between the anterior and posterior leaflets using one or two clips that are deployed through a trans-septal approach. A clip, which is mounted on the end of a catheter, is advanced through a vein from the groin into the left atrium. The clip is opened and advanced across the mitral valve. While the heart is beating, the ends of the clip latch onto the flaps of the valve pinning the leaflets together. The resulting bow-tie-shaped opening permits blood flow when the heart relaxes, but prevents leakage or back flow when the heart contracts. The MitraClip is now commercially available for high-risk patients with degenerative mitral disease, and is under evaluation – in the COAPT multicenter trial – for patients with functional mitral disease.

**MitraClip Complications Rate 2015**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postoperative Stroke</td>
<td>1.3%</td>
</tr>
<tr>
<td>Renal Failure - New Onset Dialysis</td>
<td>0.0%</td>
</tr>
<tr>
<td>30 Days Readmission - Unplanned</td>
<td>4.0%</td>
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Source: Vizient Clinical Data Base/Resource Manager™ used by permission of Vizient. All rights reserved.

**The Next Quantum Leap**

NewYork-Presbyterian is positioned at the cutting edge of the next generation of techniques to manage patients with severe and various forms of mitral valve disease. Collaboration among our surgeons and interventionalists are already paving the way toward a new chapter in percutaneous mitral valve replacement. The approach will essentially be the mitral version of transcatheter aortic valve replacement. Experimental evaluation of these devices has already begun, and four new early studies will soon begin enrolling patients for repair or replacement of the mitral valve using transcatheter techniques.

**Surgery without Bypass**

NewYork-Presbyterian/Columbia is a principal investigator center for a multicenter international study evaluating standard mitral valve repair surgery versus surgical repair using Gore-Tex neochordae via the apex of the left ventricle in all risk patients with mitral valve regurgitation. The Gore-Tex neochordae approach does not involve cardiopulmonary bypass, enabling surgeons to correct a patient’s mitral valve prolapse under normal physiologic beating-heart conditions.

**TREATMENT FOR THE TRICUSPID VALVE**

Tricuspid regurgitation is a very common condition afflicting about 1.6 million people in the United States alone. However, because tricuspid valve disease often presents in combination with right heart dysfunction, liver disease, or in patients with prior cardiac procedures, tricuspid valve surgery has been associated with a significant mortality rate. NewYork-Presbyterian physicians are leading major programs to treat patients with tricuspid regurgitation via catheter-based techniques. Columbia researchers are leading a national trial of TriAlign, an innovative catheter-based device for repair of the tricuspid valve. Through a transjugular approach, a pledgeted suture is used to cinch the valve, making the leaflets close more fully, and thereby reducing the leak. Researchers at Columbia are also evaluating the Edwards FORMA transcatheter valve system, another minimally invasive way to repair the tricuspid valve. Using a catheter, physicians place a foam-filled polymer balloon “filler” in the area of the leakage. The patient’s leaflets coapt on the balloon and this reduces regurgitation.
Selected Clinical Trials

**COAPT Trial** The purpose of the COAPT trial is to confirm the safety and effectiveness of the MitraClip® System for the treatment of moderate-to-severe or severe functional mitral regurgitation in symptomatic heart failure subjects. (Phase III)

**Concurrent Tricuspid Valve Repair During Mitral Surgery** This study will determine whether repairing a tricuspid valve in patients with mild-to-moderate tricuspid regurgitation at the time of planned mitral valve surgery will improve heart health. (Phase II)

**INTREPID** The purpose of this early feasibility study is to evaluate the safety and initial performance of the Medtronic Intrepid Transcatheter Heart Valve for treatment of mitral valve disease.

**PARTNER 3: SAPIEN 3 Transcatheter Heart** This study will establish the safety and effectiveness of the Edwards SAPIEN 3 transcatheter heart valve in patients with severe, calcific aortic stenosis who are at low operative risk for standard aortic valve replacement. (Phase III)

**ReChord** This trial will assess the effectiveness of the study device in subjects undergoing mitral valve repair without cardiopulmonary bypass compared to standard surgical techniques with cardiopulmonary bypass.

**REFLECT Trial: Cerebral Protection TAVI** This study will assess the safety and efficacy of the TriGuard™ HDH embolic deflection device in patients undergoing TAVI. (Phase II/III)

**SCOUT: Mitralign Percutaneous Tricuspid Valve Annuloplasty System** This study will assess the early safety and performance of the Mitralign Percutaneous Tricuspid Valve Annuloplasty System for symptomatic chronic functional tricuspid regurgitation.

**Tricuspid Transcatheter Repair** This early feasibility study will measure clinical outcomes and effectiveness of the Edwards FORMA Tricuspid Transcatheter Repair System.

Selected Publications


With increasing experience and research that has demonstrated proven durability of aortic root valve-sparing surgery, NewYork-Presbyterian surgeons are making these procedures available to a greater number of patients who can benefit. Aneurysm size, valve dysfunction, and age are no longer exclusionary criteria.

**Aortic Procedures**

<table>
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<th>Volume 2011 - 2015</th>
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<tr>
<td>600</td>
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<td>2011</td>
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Source: NewYork-Presbyterian
repair, further increasing the complexity of disease. The majority of these patients require custom-designed grafts. Utilizing sophisticated CT imaging, our surgeons create three-dimensional models to precisely design a stent graft built to the anatomical specifications of each individual patient.

**High-Risk Surgical Cases** NewYork-Presbyterian vascular surgeons are pursuing the development of endovascular devices for the treatment of aortic aneurysms in patients at high risk for surgery. They are currently enrolling patients in an FDA-approved clinical trial of custom-designed stent grafts for the treatment of thoracoabdominal aortic aneurysms. No stent graft treatment is currently commercially available for these patients, many of whom are over the age of 80. The minimally invasive stent graft device will allow physicians to treat thoracoabdominal aortic aneurysms without the large incisions of traditional open surgery, sparing patients the risk of major complications.

**Iliac Branch Endoprosthesis** NewYork-Presbyterian served as lead investigators of the just completed multicenter nationwide trial of the Gore® Excluder® iliac Branch Endoprosthesis, the first off-the-shelf aortic branch device approved in the country and the only device indicated for the endovascular treatment of common iliac artery aneurysms or aortoiliac aneurysms. Results of the five-year trial in which more than 565 patients were treated will be published shortly.

**Suprarenal Abdominal Aorta** Well-established endovascular techniques are available for the descending aorta and for the infrarenal abdominal aorta. Surgeons at NewYork-Presbyterian are now in the stages of development of endovascular approaches for the suprarenal abdominal aorta. Treating aneurysm disease of the ascending aorta and the aortic arch with endovascular approaches present some engineering challenges, and first generation devices are now being tested in clinical trials.

**Following the Genetic Link** Weill Cornell Medicine researchers are investigating the genetic linkage in younger individuals or individuals with a family history that may have a genetic predisposition for their aneurysm disease. Their findings have implications for specific medication therapies that are shown to be effective for preventing aneurysm disease in patients with certain hereditary aneurysm conditions such as Marfan’s. In addition, the information guides screening, as they may be harboring an aneurysm that is asymptomatic and could put them at risk for a catastrophic occurrence.
**AORTIC DISEASE**

### Selected Clinical Trials

**Endovascular Thoracoabdominal Aortic Aneurysm Repair (TAAA IDE)** This prospective, nonrandomized, single-center, single-arm study will assess the feasibility and safety of endovascular stent-graft implantation using a standard configuration branched and fenestrated stent graft or physician-specified branched and fenestrated stent grafts for treatment of thoracoabdominal aortic aneurysms involving the mesenteric and renal arteries in patients at high risk for open surgery.

**N-TA^3CT: Non-Invasive Treatment of Abdominal Aortic Aneurysm** The primary aim of this study is to determine if doxycycline will inhibit by at least 40 percent the increase in greatest transverse diameter of small abdominal aortic aneurysms (3.5-5.0 cm in men, 3.5-4.5 cm in women) over a 24-month period of observation in comparison to a placebo-treated control group. (Phase II)

**PRESERVE-Zenith® Iliac Branch System Clinical Extended Study** This trial evaluates the safety and effectiveness of the Zenith Branch Endovascular Graft-Iliac Bifurcation System, which is made up of two devices – the Zenith® Branch Endovascular Graft-Iliac Bifurcation and the ConnectSX™ covered stent – in the treatment of aorto-iliac and iliac aneurysms.

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**Open Thoracic Aortic Repair**

**Ascending Aorta and Aortic Arch In-Hospital Complications Rate 2015**

- **Acute Renal Failure - Early Onset Dialysis**: 1.0%
- **Deep Sternal Wound Infection**: 0.0%
- **Postoperative Stroke**: 1.7%

Source: NewYork-Presbyterian

**In-Hospital Mortality Rate 2015**

- **Thoracic Aortic Repair**
  - **Observed**
  - **Expected**

  "Expected mortality was determined using Vizient risk-adjustment methodology. Source: Vizient Clinical Data Base/Resource Manager™ used by permission of Vizient. All rights reserved.”

**Valve Sparing In-Hospital Mortality Rate 2015**

- **Elective**
- **Urgent/Emergent**

  "Expected mortality was determined using Vizient risk-adjustment methodology. Source: Vizient Clinical Data Base/Resource Manager™ used by permission of Vizient. All rights reserved.”

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Source: NewYork-Presbyterian
CASE STUDY:  
THORACIC ENDOVASCULAR AORTIC REPAIR

A 36-year-old male presented with increasing shortness of breath, as well as a several week history of fever and night sweats. Investigations revealed streptococcus viridans endocarditis with severe aortic regurgitation, as well as a large aortic root abscess. His past medical history was significant for aortic coarctation repair at the age of 5. Preoperative CT examination revealed a 6.0 cm aneurysm of the descending aorta (Figure 1).

The patient underwent replacement of the aortic root and ascending aorta with a “BioRoot” (i.e. pericardial valve sewn into a Gelweave graft), as well as autologous pericardial patch reconstruction of the aortic annulus and intervalvular body. His postoperative course was uncomplicated. Once the antibiotic therapy was completed, the patient underwent thoracic endovascular aortic repair (TEVAR) of the descending aorta with left subclavian-carotid bypass. The perioperative course was uncomplicated and the patient was discharged home on day 3. He is alive and well one year postoperatively with an unremarkable follow-up CT scan (Figure 2).

Selected Publications


(continued on page 47)
CASE STUDY: TYPE B AORTIC DISSECTION

A 44-year-old male with a history of hypertension presented to an outside hospital with acute onset tearing chest and back pain. A CT scan revealed an acute type B aortic dissection extending from the left subclavian artery to the iliac arteries. He was managed medically with antihypertensive medications and discharged home. He presented to NewYork-Presbyterian four days later with acute worsening of chest pain radiating to the neck and back. He had severe hypertension that required multiple different antihypertensive medications to control. He had persistent pain as well. An endovascular stent graft was placed in his descending thoracic aorta, covering the primary tear of the dissection. His pain resolved and his blood pressure was better controlled with fewer medications.
**Endovascular Abdominal Aortic Repair (EVAR)**

### Procedure Volume by Location 2015

- **Infra-renal**: 39% (n=33)
- **Iliac**: 34% (n=28)
- **Iliac, Juxtarenal**: 4% (n=4)
- **Iliac, Supra-renal**: 3% (n=2)

Source: NewYork-Presbyterian

### In-Hospital Complications Rate 2015

- Acute Renal Failure - Early Onset Dialysis: 0.0%
- Deep Sternal Wound Infection: 0.0%
- Postoperative Stroke: 0.0%
- 30 Days Readmission - Unplanned: 2.4%

Source: NewYork-Presbyterian

### In-Hospital Mortality Rate 2015

- **All EVAR**: 0%
- **Elective**: 0%
- **Emergent/Urgent**: 0%

*Expected mortality was determined using Vizient risk-adjustment methodology. Source: Vizient Clinical Data Base/Resource Manager™ used by permission of Vizient. All rights reserved.

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**Selected Publications**

(continued from page 45)


CEREBROVASCULAR DISEASE

Selected Clinical Trials

CREST-2: Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial
Weill Cornell Medicine and Columbia University Medical Center are participating in the NIH-funded multicenter CREST-2 study of carotid treatment for patients with asymptomatic carotid atherosclerotic stenosis. The study compares a combination of carotid endarterectomy and intensive medical management to intensive medical management alone, and carotid artery stenting combined with intensive medical management to intensive medical management alone, in two separate arms. Columbia and Weill Cornell are the only sites in New York City participating in CREST-2.

Selected Publications


CAROTID ARTERY DISEASE

NewYork-Presbyterian’s vascular and endovascular surgery centers are among the highest volume programs in New York State, providing traditional vascular procedures as well as innovative and minimally invasive endovascular therapies. Our specialists offer comprehensive treatments for carotid artery disease and cerebrovascular disease to prevent stroke, including medical management, endarterectomy, and more minimally invasive carotid artery stenting. We emphasize less invasive treatments that shorten recovery time and improve patient outcomes. Our physicians are performing fewer carotid interventions, largely for patients with asymptomatic disease, because they believe that medical therapy in many cases may be preferable.

NewYork-Presbyterian’s vascular and endovascular surgery centers are among the highest volume programs in New York State.

Our endovascular specialists provide expertise in screening and surveillance with noninvasive tests, including carotid ultrasound, CT angiography, and MR angiography. Patients benefit from our state-of-the-art endovascular operating room suites that combine robotics and 3-D imaging, enabling us to safely perform the most advanced endovascular treatments available today.

Transcarotid Revascularization (TCAR) NewYork-Presbyterian physicians are helping to develop a nationwide multicenter clinical trial and registry studies designed to monitor the safety and effectiveness of stents placed directly into the carotid artery while reversing blood flow within the carotid artery to reduce stroke risk. Surgeons access the carotid artery through a mini incision at the base of the neck using local anesthetic rather than accessing the artery remotely with catheters from the groin, thereby avoiding the risks of entering through complex aortic arch anatomy. The remainder of the procedure is performed with a stenting technique, providing embolic protection. Our surgeons still apply advanced stenting technology, but more safely in that they can control blood flow in the artery and prevent debris, fragments, or embolization to the brain that can cause stroke.
Carotid Artery Procedures

Volume 2011 - 2015

Procedure Volume by Type 2011 - 2015

In-Hospital Mortality Rate 2015

Adverse Events Perioperative through 30 Days Post-Procedure 2015

Myocardial Infarction

Stroke

Death

Benchmark Source: Joint Commission on Accreditation of Healthcare Organizations; Advanced Disease-Specific Care Certification Requirements for Comprehensive Stroke Center (CSC) 2015
NewYork-Presbyterian brings together vascular specialists in cardiology, radiology, and vascular surgery for the management of patients with peripheral vascular disease. For lower extremity disease, patients receive targeted therapies to manage limb-threatening ischemia, non-healing wounds, pain with walking, and diabetes. We provide medical management, as well as catheter-based minimally invasive procedures, and surgical bypass, with minimally invasive revascularization techniques utilized whenever possible.

**Program for Advanced Limb Preservation** NewYork-Presbyterian specializes in treating lower extremity wounds in patients at high risk for amputation, particularly those with diabetes and peripheral artery disease. Patients with diabetes oftentimes have multiple medical conditions and severe vascular disease that lead to tissue breakdown and the formation of wounds and ulcers, development of pain at rest, and gangrene in the foot, toes, or limb. Our physicians are skilled in emergent revascularization for these patients, as well as managing their myriad and complex comorbidities, including heart disease and renal failure.

Through the Program for Advanced Limb Preservation, an interdisciplinary team of vascular specialists, podiatrists, plastic surgeons, and other experts is dedicated solely to healing wounds and preventing amputations in patients with diabetes, PAD, and other vascular problems. The program is New York City’s only tertiary limb salvage program providing comprehensive diagnostic evaluation, advanced wound care treatments, including hyperbaric oxygen therapy, surgical and minimally invasive vascular procedures, reconstructive foot surgery, and investigational treatments such as stem cell therapy.

**Vascular Diagnostic Laboratory** NewYork-Presbyterian’s Vascular Diagnostic Laboratory provides advanced diagnosis, treatment, and prevention approaches for diseases of the vascular or circulatory system. Comprised of three dedicated labs and two advanced treatment rooms for minimally invasive procedures, the Vascular Diagnostic Laboratory performs a wide array of noninvasive vascular studies. Among the testing modalities are carotid duplex ultrasound, aortic ultrasound, venous ultrasound, vein mapping, arterial duplex imaging of upper and lower extremities, digital photoplethysmography, and thoracic outlet syndrome evaluation.
Peripheral Vascular Procedures

Peripheral Arterial Revascularization Procedures 2011 - 2015

Selected Clinical Trials

**BEST-CLI: Best Endovascular versus Best Surgical Therapy for Critical Limb Ischemia**  This study compares the effectiveness of the best available surgical treatment with the best available endovascular treatment in adults with critical limb ischemia who are eligible for both treatment options.

**WISE LE: Evaluation of WIRION™ EPS in Lower Extremities Arteries**  This study seeks to demonstrate the safety and performance of the WIRION EPS in patients undergoing lower extremity atherectomy for peripheral arterial disease.

Selected Publications


NewYork-Presbyterian is home to dedicated adult cardiovascular imaging programs that are among the largest in the world. Our cardiovascular imaging specialists continually investigate and develop emerging technologies and techniques in this burgeoning field.

Non-ischemic fibrosis (NIF) on cardiac magnetic resonance has been linked to poor prognosis. A study by Weill Cornell Medicine researchers examining a broad cohort of patients with right ventricular (RV) dysfunction supports the concept that NIF is linked to adverse RV chamber remodeling. Shown here are representative examples of each RV dimension; all were measured during both end-diastole and end-systole.


Imaging specialists at NewYork-Presbyterian employ a multidisciplinary, multi-modality approach to the detection and treatment of heart disease, including ischemic, valvular, and congenital heart disease, and thoracic disorders. Our cardiovascular imaging programs bring together cardiologists with training in advanced cardiac imaging and radiologists who, in addition to the traditional cardiac imaging tools, apply MRI, CT, and PET imaging in new and novel ways, including combining these techniques with other cutting-edge diagnostic tests to improve detection and guidance for treatment.

**Imaging in Adult Congenital Heart Disease** Emerging imaging technologies are affording a better understanding of the anatomic and physiologic aspects of congenital heart disease in adults. MRI provides incredibly high spatial resolution imaging for both cardiac function and cardiac morphology, but also looks specifically at physiologic aspects of both left and right ventricular function, as well as valvular flow function and anatomy – all within a single, multifaceted examination. Unlike other cardiovascular imaging modalities, MRI can wed these abilities and multifaceted imaging approaches to the direct assessment of myocardial tissue characteristics, which is especially applicable to patients with adult congenital heart disease. In these patients, our cardiologists are interested in long-term sequential monitoring of cardiovascular performance. Increasingly, our physicians are gathering data that not only show where the MRI can detect changes, but also how the changes that are detected are prognostically significant, helping, for example, to better stratify those patients who will need surgery or to predict who will have arrhythmic events.

For patients who cannot have an MRI scan due to having a pacemaker or a defibrillator, our physicians are also using 320-slice cardiac CT in a novel way to evaluate the function of the patient’s heart. Using gated CT, they have been able to reduce the radiation exposure by about 80 percent while still achieving very high resolution images of heart function, valves, and vessels.

**An Emphasis on Early Identification** Our imaging specialists have a particular interest in improving methods for early identification of heart disease in women, ethnic minorities, and young patients with a family history of premature heart disease. Their
expertise includes coronary artery calcium scoring for asymptomatic individuals at high risk of disease, and cardiac PET that allows visualization of microvascular circulation that can cause chest pain in patients whose larger arteries are free of disease.

**Coronary Calcification Test** A study by Weill Cornell researchers has demonstrated that the coronary artery calcification test, a five minute procedure that examines the total amount of calcified plaque buildup in the heart arteries, can be used to accurately predict the likelihood of heart attack or death over a 15-year period. With this information, physicians can intervene earlier and more aggressively if the non-invasive scan shows a patient is at risk for heart disease but not yet having symptoms.

**Diagnosing ATTR-CA** A type of heart failure caused by a build-up of amyloid can be accurately diagnosed and prognosticated with an imaging technique, eliminating the need for a biopsy in select patients, according to a multicenter study led by researchers at Columbia University Medical Center. The technique may also detect transthyretin-related cardiac amyloidosis (ATTR-CA) before it progresses to advanced heart failure. The diagnostic tool evaluated in the study, technetium pyrophosphate planar cardiac imaging, is derived from bone scintigraphy, a form of single-photon emission computed tomography that is conventionally used to detect bone cancer. The imaging scans were compared to tissue biopsy results, the gold standard for diagnosing ATTR-CA.

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**Selected Publications**


Sleep and Heart Disease in Women  Columbia researchers have launched a study to learn if inadequate sleep increases the risk of heart disease in women. With funding from the American Heart Association, they are enrolling 500 women between the ages of 20 and 79 to examine sleep patterns and other potential risk factors, including menopause and caregiving and relationship stressors. They will also look at molecular changes that occur with restricted sleep and how those changes raise the risk of heart disease.

Women’s Heart Alliance  The Women’s Heart Alliance is a collaboration between the Barbra Streisand Women’s Heart Center at Cedars-Sinai Heart Institute and the Ronald O. Perelman Heart Institute at NewYork-Presbyterian/Weill Cornell Medical Center. Education and advocacy efforts have included participation in the Women in the World Summit focused on heart disease outcomes and meetings on Capitol Hill to discuss legislation on equitable representation of heart disease in women in medical research.

HeartSmarts  In 2016, NewYork-Presbyterian/Weill Cornell marked the fifth anniversary of its HeartSmarts program, which aims to reduce the incidence of cardiovascular disease through education in underserved communities. In collaboration with churches and wellness ministries, the program has created a coalition of more than 80 lay health ambassadors who utilize a faith-based curriculum to increase knowledge of cardiovascular health and heart disease prevention. A recent study by Weill Cornell Medicine researchers demonstrated that a 12-week HeartSmarts program resulted in significant reductions in participant averages for systolic and diastolic blood pressure, weight, and BMI.

Heart Health in Action  Launched more than a decade ago, Columbia’s Heart Health in Action program is designed to improve awareness and knowledge of cardiovascular disease among a high-risk population of urban minority women. Since its inception, more than 1,000 women ranging from age 19 to 90 have been assessed for their cardiovascular disease (CVD) knowledge and screened for metabolic syndrome, including hypertension, an abnormal lipid profile, high blood sugar, and increased waist size. A major goal of the program is to help participants take steps to reduce weight and increase physical activity. Columbia researchers recently evaluated a segment of the population—women 18 to 49—for cardiovascular disease risk burden and found the majority were at high risk, particularly among those overweight and physically inactive. Strategies to encourage healthy lifestyles and reduce CVD risk factors among this vulnerable at-risk population are vital.

PCSK9 and Cardiac Prevention  Weill Cornell Medicine researchers are evaluating the use of PCSK9 inhibitors to control the number of low-density lipoprotein receptors that play a critical role in regulating blood cholesterol levels in individuals who cannot tolerate statins or who may not be achieving their goals on statin therapy.

Individuals Uniquely at Risk  Weill Cornell researchers are identifying individuals at risk for heart disease due to lipid disorders, family history of heart disease at young ages, inflammatory disorders, and premature menopause. They also have found that women who have survived cancer may not be screened as rigorously for heart disease because of the intense focus on their cancer. Importantly, imaging for breast cancer staging can potentially identify calcium in the arteries, and those women so identified should be referred to a cardiologist for preventive therapies.

Selected Publications


Columbia University Medical Center is making important contributions to cardiovascular behavioral medicine research with a team of highly skilled interdisciplinary professionals – internists, cardiologists, psychologists, and quantitative faculty. They are engaged in research studies investigating:

- Behavioral and biological factors that explain the relationship between psychological factors and heart disease
- Ways to treat depression in those with established heart disease
- Modifiable emergency department and patient-level factors that can improve care, reduce recurrence, and minimize rehospitalization
- Mechanisms connecting psychological, emotional, and physical health
- Psychosocial factors and biological mechanisms that contribute to hypertension
- Alternative approaches to diagnosing and treating hypertension

Their scientific investigations will increase the understanding of the mechanisms involved in cardiovascular diseases. With recognition of the importance of behavioral, psychological, societal, and lifestyle factors, they will be able to improve management of the risks of hypertension and heart disease. Current research endeavors include:

**REACH: Reactions to Acute Care and Hospitalization** This study is designed to identify emergency department factors associated with poor long-term psychiatric and medical prognosis after cardiac events.

**Post-Hospital Syndrome** This study aims to determine best hospital practices for reducing readmission risk in cardiac patients.

**CODIACS Quality of Life** This study seeks to determine the quality-adjusted life year benefits and healthcare costs of following the American Heart Association’s advisory for depression screening and subsequent comprehensive treatment of depression in cardiac patients.

**PUME** This study is examining the acute effects of provoked anger, depressed mood, and anxiety on vascular endothelial cell health.

**Ambulatory Blood Pressure Monitoring Implementation** This study involves the development and testing of an intervention to increase uptake of the U.S. Preventive Services Task Force hypertension screening guidelines in diverse primary care settings.

### Selected Publications


In July 2016, NewYork-Presbyterian introduced NYP OnDemand, a suite of digital health services designed to improve and expand patient care in new and innovative ways. NYP OnDemand was created by members of the Department of Information Technology under the direction of Daniel Barchi, Senior Vice President and Chief Information Officer, and Peter M. Fleischut, MD, Chief Innovation Officer, in concert with the Hospital’s clinical team.

NYP OnDemand is comprised of telehealth services for both patients and healthcare providers and includes:

**Second Opinion** Patients can receive detailed written second opinions on their diagnosis or treatment from world-renowned specialists at Columbia University Medical Center and Weill Cornell Medicine through a secure, easily accessible online service.

**Digital Emergency** At NewYork-Presbyterian/Weill Cornell Medical Center, patients visiting the Emergency Department with non-life threatening illnesses and injuries can have a live video visit with an Emergency Medicine physician. The first program of its kind in New York, the program has reduced ED admission to discharge time from 2.5 hours to less than 35 minutes.

**Urgent Care** Adults in New York State can have a live video visit with a Weill Cornell Medicine Emergency Medicine physician from their phone, tablet, or desktop. Patients can receive care for non-life threatening illnesses and injuries such as the flu, a sore throat, or allergies, all from the comfort of home.

**Virtual Visit** Patients can have a live video visit with their medical professional from their phone, tablet, or desktop, saving time and making these visits more convenient.

**Inter-Hospital Consult** Providers across NewYork-Presbyterian’s hospital sites can collaborate on cases and provide their specialty insight to patients and their colleagues. NewYork-Presbyterian’s Inter-Hospital Consult programs include Telestroke, Telepediatrics, and a Mobile Stroke Treatment Unit.

“At NewYork-Presbyterian, we are looking to redefine the intersection of technology and healthcare, and our new digital health platform is our way of strengthening traditional telehealth services.”

Dr. Steven J. Corwin
President and CEO
NewYork-Presbyterian