

CASE STUDY Limb Preservation through Multidisciplinary Teamwork and Complex Treatment

Procedures

A 64-year-old man with diabetes, hypertension, and renal failure presented to the Limb Preservation Program at the Robert Wood Johnson University Hospital (RWJ) with limb-threatening ischemia of the left leg and gangrene in three toes, along with ischemia of the right leg. Previous treatment elsewhere had left the patient with stents in both legs from the hip to past the knee as well as in the abdominal aorta, making a traditional approach to endovascular revascularization impossible. Nor was the patient a candidate for surgical bypass due to his co-morbidities and the extensive stenting.

Innovative Approach Provides Access to Unreachable Lesion

"At any other center, the patient would have had a bi-lateral amputation," said Ashish Awasthi, MD, Co-Director of RWJ's Peripheral Endovascular Program and an Interventional Cardiologist at the hospital. Dr. Awasthi collaborated with Vascular Surgeon Paul Haser, MD, Associate Professor of Surgery at Robert Wood Johnson Medical School and Co-Director of RWJ's Peripheral Endovascular Program, which focuses on decreasing the rate of

limb loss due to critical limb ischemia through seamless collaboration between vascular surgeons and interventional cardiologists.

Initially, Dr. Awasthi performed percutaneous transluminal angioplasty and cryoablation by accessing the occlusion via the patient's arm. However, with the devices and technology available at that time (2008), he could not reach below the knee. "We didn't give up," said Dr. Awasthi. He and Dr. Haser decided to try accessing the occlusion below the knee through the patient's lower leg. Performing this lengthy, technically demanding procedure together, they achieved successful revascularization.

"That's the type of thing you can do when you have a collaborative approach rather than a serial approach," said Dr. Haser. "We have the skill set to employ the basic approaches and the creativity to attempt different approaches to access lesions that would otherwise be out of reach." The podiatrist who referred the patient to RWJ amputated part of the patient's big toe and the next two toes. When the patient's right leg reached critical limb ischemia a few months later, Drs. Awasthi and Haser were able to perform successful endovascular revascularization.

Collaborative Treatment Using State-of-the-Art Endovascular Devices

Despite aggressive re-stenosis and multiple revascularization procedures over the next few years, the patient still has use of both legs. This outcome is only possible because of the continued collaboration of Drs. Awasthi and Haser, combined with use of state-of-the-art endovascular devices that are now available, such as the CVX-300® Excimer Laser System. "My interventional colleagues bring their most difficult vascular cases to RWJ because they know we have collaborative help available from Paul and his team," said Dr. Awasthi.

For more information on the Limb Salvage Program, please call Donna Prete, RN, Cardiovascular Center of Excellence Nurse Coordinator, at 1-855-RWJLEGS (795-5347).

"We have the skill set to employ the basic approaches and the creativity to attempt different approaches to reach lesions that would otherwise be out of reach."

Paul Haser, MD



FACULTY LEADERSHIP New Chief to Build a Leading Cardiothoracic Surgery Program

Ever since Leonard Y. Lee, MD, FACS, FACC, FCCP, attended Robert Wood Johnson Medical School he has believed that the medical school and Robert Wood Johnson University Hospital (RWJ) were well positioned to become a leading cardiothoracic surgery program. "The volume, the quality of care, and the academics are tremendous," said Lee, the new Chief of the Division of Cardiothoracic Surgery at Robert Wood Johnson Medical School and RWJ.

"My goals are to increase outreach to new patients, increase the program's academic profile, and ensure that more people regionally and nationally know about our program," he said. Dr. Lee comes to Robert Wood Johnson Medical School and RWJ from Hackensack University Medical Center where he was Vice Chair of the Heart and Vascular Hospital and Chief of the Division of Cardiothoracic Surgery and before that, Director

of Advanced Aortic and Valvular Heart Surgery. He was also the Chief of the Division of Cardiothoracic Surgery and Director of the Cardiac Surgery Program at New York Methodist-Cornell Heart Center.

Consistently named a "best" or "top" doctor by New York Magazine, Castle Connolly, Consumer Research Council of America, and Vitals.com, Dr. Lee's clinical interests are thoracic aortic aneurysm repairs and minimally-invasive mitral valve repairs. His research has focused on using adenoviruses in gene therapy to trigger revascularization of ischemic cardiac tissue and localized cardiac inflammation. He hopes to extend the former research by using stem cells to repair cardiac damage.

For more information on Dr. Lee, please call 732-235-8725.

Dr. Lee's Education and Training

Education

- MD: Robert Wood Johnson Medical School
- BA in Biology: Lehigh University

Training

- General Surgery Chief Resident, St. Vincent's Hospital and Medical Center

Fellowships:

- Cardiothoracic Clinical Fellow:
 - o Memorial Sloan Kettering Cancer Center
 - o New York Presbyterian Hospital-Weill Medical College of Cornell University
- Medicine Fellow (Research)
 - o New York Presbyterian Hospital-Weill Medical College of Cornell University



One Robert Wood Johnson Place
New Brunswick, NJ 08903



Cardiovascular Program Leadership

James Coronilas, MD
Professor of Medicine
Robert Wood Johnson Medical School
Chief of Cardiology
Robert Wood Johnson University Hospital

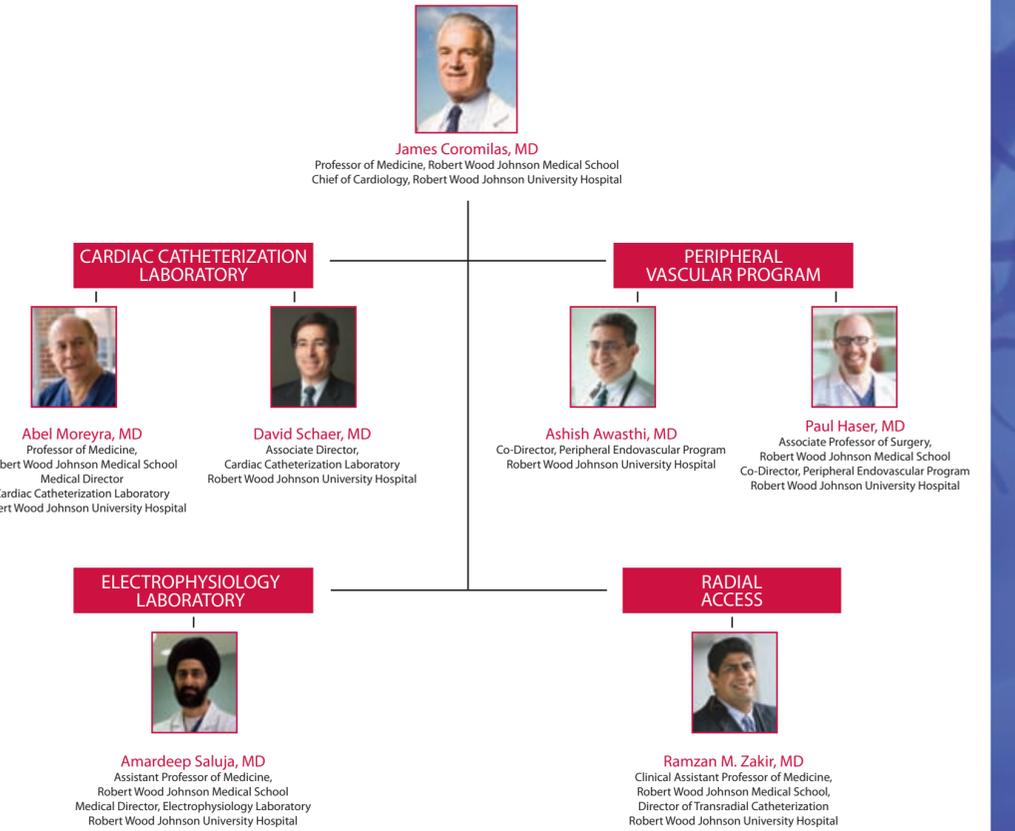
Alan Graham, MD
The Norman and Ruth H. Rosenberg Professor
of Vascular Surgery
Interim Chair of Surgery
Robert Wood Johnson Medical School
Chief of Vascular Surgery
Robert Wood Johnson University Hospital

Leonard Lee, MD
Professor of Surgery
Robert Wood Johnson Medical School
Chief of Cardiothoracic Surgery
Robert Wood Johnson University Hospital

RWJUH Cardiovascular Connection
Committee Members
Michael Antoniadis, MPA
Vice President, Operations
Robert Wood Johnson University Hospital

Margaret Ames, MPA, BSN, RN
Administrative Director, Cardiac and Transplant Services
Robert Wood Johnson University Hospital

CARDIOLOGY AT ROBERT WOOD JOHNSON UNIVERSITY HOSPITAL



Ventricular Assist Device Team Expands Knowledge

Six members of the Robert Wood Johnson University Hospital (RWJ) ventricular assist device (VAD) team participated in a two-day HeartMate II (HMII) Left Ventricular Assist System advanced workshop with the VAD team at Integris Baptist Hospital, a high-volume VAD center in Oklahoma City. The HMII is used as a bridge to heart transplantation or, in non-transplant candidates, as destination therapy.

Thoratec, manufacturer of the HMII and other mechanical circulatory support devices for advanced heart failure, selected RWJ to participate in the June 2012 workshop because of its excellent outcomes (97 percent survival at 30 days and 84 percent at one year based on 32 implants since 2009) and potential for serving more patients with the HMII. Also, RWJ is one of a few hospitals in New Jersey with advanced certification in VAD for destination therapy from The Joint Commission.

"We have everything in place to expand our use of the HMII," said George P. Batsides, MD,

Assistant Professor of Surgery at Robert Wood Johnson Medical School and a Cardiothoracic Surgeon at RWJ. Dr. Batsides was one of the participants in the workshop, during which the Integris Baptist Hospital VAD team shared its procedures for patient selection, transplant and heart failure case reviews, post-op management, long-term outpatient management and more. Both teams presented case studies.

For more information on VADs at RWJ, please call (732) 253-3699.

The Mechanical Circulatory Support Program at RWJ

Short-term devices for myocardial recovery:

- Impella 2.5 and 5.0
- LVAD AB5000
- R/L/ Bi-VAD

Long-term device:

- Heartmate II



Robert Wood Johnson University Hospital
Cardiovascular Connection
Updates

www.rwjuh.edu/heart

PROCEDURES/NEW TECHNOLOGY Transradial Catheterization Leads to Fewer Complications and Better Outcomes

Transradial catheterization, available at Robert Wood Johnson University Hospital (RWJ), significantly reduces access-site bleeding, including in extremely obese patients, when compared to conventional transfemoral catheterization. In patients with ST-segment elevation acute coronary syndrome, the transradial approach significantly reduces mortality. "Major bleeding in these patients is a strong predictor of morbidity and mortality and even has a worse prognosis than recurrent myocardial infarction in the first month. By reducing bleeding complications so well, the transradial approach in patients with STEMI reduces cardiac mortality and hospital stay," said Ramzan M. Zakir, MD, FACC, FSCAI, Clinical Assistant Professor of Medicine, Robert Wood Johnson Medical School and Director of Transradial Catheterization at RWJ. Dr. Zakir has performed more than 1,000 transradial catheterizations.

Studies Show Benefits of Transradial Approach

Studies such as RIVAL¹ and RIFLE-STEACS² have shown these and other benefits. RIVAL compared the transradial and transfemoral approaches for coronary intervention in 7,021 patients with acute coronary syndrome from 158 hospitals in 32 countries. Patients were randomized to radial access (3,507 patients) or femoral access (3,514 patients). The primary outcome, a composite of death, myocardial infarction, stroke, or non-coronary artery bypass graft (non-CABG)-related major bleeding at 30 days, occurred in 128 (3.7%) patients in the radial access group compared with 139 (4%) patients in the femoral access group. This study also showed reductions in mortality in patients with ST-segment elevation acute coronary syndrome, however, it was not adequately powered to detect these differences.

RIFLE-STEACS evaluated whether the transradial approach is associated with better outcomes in patients with ST-segment elevation acute coronary syndrome compared with transfemoral access. The four-center study randomized 1,001 patients with ST-segment elevation acute coronary syndrome who were undergoing percutaneous coronary intervention to the radial (500) or femoral (501) approach. The primary endpoint was the 30-day rate of net adverse clinical events (NACEs), a composite of cardiac death, stroke, myocardial infarction, target lesion revascularization, and bleeding. This occurred in 68 (13.6%) radial access patients and 105 (21.0%) femoral access patients. Radial access was associated with significantly lower rates of cardiac mortality (5.2% vs. 9.2%), bleeding (7.8% vs. 12.2%), and shorter hospital stay (5 days [range: 4-7 days] vs. 6 days [range: 5-8 days]) than femoral access. The investigators concluded that the lower morbidity and cardiac mortality with radial access should make it the recommended approach in patients with ST-segment elevation acute coronary syndrome, provided there is adequate operator and center expertise.

Another single-center study³ compared angiography and percutaneous coronary intervention in 564 extremely obese patients: 361 (64%) in the transfemoral group and 203 (36%) in the transradial group. The primary

Learn to Perform Transradial Catheterization
Dr. Zakir teaches a one-day course in transradial catheterization at RWJ. After a didactic lecture in the morning, participating physicians perform the procedure with Dr. Zakir in the afternoon. So far, about 12 physicians have taken the course. "Many have gone on to become primarily radial operators," said Dr. Zakir. The course is offered throughout the year and is open to interventional cardiologists throughout the United States.



outcome, a combined endpoint of major bleeding, access-site complications, and non-access site complications, occurred in 7.5% of the transfemoral group and 2.0% of the transradial group.

Other benefits of transradial catheterization include improved patient comfort and recovery time and decreased hospital utilization. Patients do not need to lay flat for up to six hours after transradial catheterization and can move around almost immediately, depending on their level of sedation. Overnight hospitalization to monitor for groin complications can be eliminated allowing for same day discharge in select patients undergoing elective PCI.

Many Uses for Transradial Catheterization
Transradial catheterization is suitable for most coronary interventions and "the vast majority of patients are excellent candidates for the transradial approach," says Dr. Zakir. Contraindications include abnormal Allen test findings, an arteriovenous fistula in the arm, or poor hand perfusion.

For more information on transradial catheterization, please call **732-418-8540**.

¹Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): a randomized, parallel group, multicenter trial. *The Lancet*, April 2011 (377, 9775): 1409-1420.

²Radial Versus Femoral Randomized Investigation in ST-Segment Elevation Acute Coronary Syndrome: The RIFLE-STEACS (Radial Versus Femoral Randomized Investigation in ST-Elevation Acute Coronary Syndrome) Study. *Journal of the American College of Cardiology*, 2012;doi:10.1016/j.jacc.2012.06.017

³Transradial versus transfemoral artery approach for coronary angiography and percutaneous coronary intervention in the extremely obese. *JACC: Coronary Intervention*, 2012 Aug 5(8):819-26.

PROCEDURES/NEW TECHNOLOGY The Appropriate Use of ICDs

The implantable cardioverter-defibrillator (ICD) has revolutionized the treatment of patients at risk for sudden cardiac death due to ventricular tachycardia (VT) or ventricular fibrillation (VF). "In multiple large clinical trials, ICDs have been shown to decrease mortality. You can't say that about many interventions in medicine," said Amardeep Saluja, MD, Assistant Professor of Medicine at Robert Wood Johnson Medical School and Medical Director of the Electrophysiology Laboratory at Robert Wood Johnson University Hospital (RWJ). RWJ has one of highest volumes for ICD implantation in New Jersey — 727 procedures in 2011, and expertise in all types of devices, including biventricular pacemakers.

ICD Indications

Despite their proven effectiveness, the indications for ICDs are complex. The device is clearly indicated, and reimbursable by the Centers for Medicare & Medicaid Services (CMS), as secondary prevention in patients with known arrhythmias and those who have survived a sudden cardiac arrest that is due to VT and VF, not to a transient or reversible cause.

Most ICDs today, however, are used for primary prevention in patients who have not had ventricular arrhythmias or experienced sudden cardiac arrest but have other significant risk factors for life-threatening VT or VF. In these cases, the patient's condition and, if applicable, the amount of time since a myocardial infarction (MI) or cardiac intervention, determine whether Medicare will cover an ICD. Medicare's covered indications for primary prevention can be summarized as:

- Ischemic cardiomyopathy and ejection fraction \leq 30% 40 days post MI > 3 months past last intervention.
- Ejection fraction \leq 35% regardless of cause (ie ischemic or non-ischemic) > 40 days post MI and > 3 months past last intervention with symptoms of heart failure.
- Less common familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome, hypertrophic cardiomyopathy or Brugada syndrome.
- Patients that demonstrate VT on invasive EP testing.

Patients meeting these criteria who have had coronary artery bypass graft surgery (CABG) or percutaneous transluminal coronary angioplasty (PTCA) must wait at least three months before ICD implantation at RWJ. The standard wait time is at least nine months, however, CMS allows hospitals that participate in the Medicare ICD Registry*, such as RWJ, to implant the device after three months. Patients who are not yet eligible for an ICD due to the CMS wait times are often referred to RWJ. "The fine print in the CMS guidelines is easily forgotten," said Dr. Saluja. "Patients need to have the problem for more than a certain period of time and not have had recent (within 3 months) bypass or stenting to qualify for an ICD." In most cases, electrophysiologists reevaluate these patients again in several months. In some cases, they protect the patient until then with a wearable defibrillator.

Ensuring the Appropriate Use of ICDs

To ensure that ICDs are implanted appropriately at RWJ, electrophysiologists must complete an indications form before booking the procedure. If the use of the ICD does not meet the CMS criteria, the physician must clearly document the reason for the ICD and the form is reviewed. The form must be approved by, the Quality Assurance Committee. Dr. Saluja notes that some patients fall outside the CMS criteria. In those cases, "we need to do what's best for the patient no matter what the guidelines say, because that's the essence of being a physician," he said.

For more information on ICDs, please call **732-418-8540**.

*Maintained by the American College of Cardiology's National Cardiovascular Data Registry, the Medicare ICD Registry covers ICDs used in primary prevention.



Timelines for ICDs in Primary Prevention at RWJ

- The need to wait > 3 months after bypass or stenting and the requirement for waiting 40 days after MI is true of all primary prophylaxis indications.
- Nonischemic patients with EF less than or equal to 35% or ischemic patients with EF between 30 and 35% with symptoms need to have those F measurements for 9 months (or 3 months if their hospital participates in a registry, which we do).



STAFF Facilitating Program Excellence and Growth Through Staff Promotions and New Hires

The Cardiovascular Center of Excellence at Robert Wood Johnson University Hospital (RWJ) is expanding its focus on high-quality care and program growth through staff promotions and new hires.



Michael A. Antoniadis
Vice President, Cardiovascular and Transplant Services

Vice President of Operations Michael A. Antoniadis, MPA, now oversees Cardiovascular and Transplant Services, which includes cardiac surgery, the catheterization and EP laboratories, cardiodynamics, cardiac rehabilitation and solid organ transplants.

"RWJ has been at the forefront of providing leading edge cardiovascular services to our patients in New Jersey and the communities we serve. With our committed physician partners in the community and the Robert Wood Johnson Medical School faculty physicians we provide a full array of services, ranging from prevention and diagnostics, to interventional, non-invasive and transplantation. We are thankful to our physician partners for choosing RWJ to provide care for their patients and proud to be the leading provider of cardiovascular services in New Jersey." Before that, he was Vice President of Operations at University Medical Center in Princeton.



Margaret M. Ames, RN, BSN, MPA
Assistant Vice President, Cardiovascular and Transplant Services

Margaret M. Ames, RN, BSN, MPA, recently was promoted to Assistant Vice President of Cardiovascular and Transplant Services. To enable RWJ to become the leading provider of cardiovascular and transplant care in the state, Ames is focusing on the continued provision of comprehensive, high-quality, collaborative care and augmenting the research program.

"RWJ offers the full spectrum of cardiovascular services, including Stereotaxis, transcatheter aortic valve replacement, heart transplants, and limb preservation," said Ames, who joined RWJ in 2006 and has been Administrative Director of Transplant Services, and Acting Administrative Director and a Research Coordinator of the Kidney and Pancreas Transplant Service. Before that, she was the Senior Clinical Coordinator for Hepatobiliary Surgery and Liver Transplantation at another hospital.

Call **732-937-8783**



Karen Malagrino, RN, MSN, CCTC
Heart Transplant

Karen Malagrino, RN, MSN, CCTC, is the Interim Administrative Director of the Transplant Center (heart, kidney and pancreas transplants). "Our heart transplant program is growing and our outcomes – a 97 percent patient survival rate after 1 year – are superb," said Malagrino, who joined RWJ in 2011 as the Kidney and Pancreas Transplant Coordinator. She previously held the same position at Our Lady of Lourdes Medical Center.

Call **732-253-3699**



Pamela Neuman, MPA
Non-Invasive Cardiovascular Services

Pamela Neuman, MPA joined RWJ in 2012 as the Director of Non-Invasive Cardiovascular Services, which includes Cardiac Rehabilitation and Cardiodynamics.

"We will continue to provide premier non-invasive cardiovascular services in each of these areas, to both our community and referring physicians, as well as their patients," she said.

Most recently, she served as the Transition Manager for the hospital relocation of the new University Medical Center of Princeton at Plainsboro. Additionally, during her tenure there, she held progressive management positions within Nursing Administration.

Call **732-937-8831**



Donna M. Prete, BSN, RN-BC, NE-BC
Transcatheter Aortic Valve Replacement

Donna M. Prete, BSN, RN-BC, NE-BC, is Clinical Coordinator for Transcatheter Aortic Valve Replacement (TAVR) and limb preservation. RWJ is one of the first centers to offer TAVR, which allows a diseased native heart valve to be replaced without open-heart surgery in selected patients with severe symptomatic aortic stenosis. "I provide education and am the person patients can reach out to," said Prete, who also coordinates care between patients and physicians. She has worked at RWJ since 1994, primarily as a Nursing Director, Head Nurse or Nurse in medical cardiology and renal failure/renal and pancreas transplant.

Call **1-855-RWJTAVR (795-8287)**



Ginell Walker-Way, RN MAS MBA
Cardiac Catheterization Laboratory

RWJ's Cardiac Catheterization Laboratory is poised to become the top center for cardiac catheterization in New Jersey, according to Director Ginell Walker-Way, RN, MAS, MBA. "We offer quality care, state-of-the-art technology, and easy access to services. Our goal is to exceed national benchmarks," she said. Walker-Way joined RWJ from Atlantic Health, where she coordinated and managed the Cardiac Catheterization/EP Lab.

Call **732-937-8748**