

the cardiovascular news beat

*A Strategic Vision in
Cardiovascular Medicine*

TWO PERCUTANEOUS VADS IMPLANTED

The first two percutaneous ventricular assist devices (VADs) implanted at the Saint Barnabas Heart Center at Newark Beth Israel Medical Center (NBIMC) illustrate two different clinical applications of the Impella device.

Approved by the FDA last year, the Impella is the only mechanical circulatory assist device that can be placed minimally invasively through a catheter-based procedure. Up to 2.5 liters of blood per minute are delivered by the pump from the left ventricle into the ascending aorta, providing the heart with active support in critical situations.

The first case was an emergent placement of the device by David Baran, MD, Director of Heart Failure and Transplant Research, in a 60-year-old-male patient who was transferred to NBIMC following a massive heart attack. "His coronary arteries had opened spontaneously but there was tremendous damage to the heart muscle," explained Dr. Baran. "The big advantage with this device is that it can be placed quickly in the Cath Lab and removed at the bedside," he added.

Within days, the scheduled implantation of a second Impella was led by Marc Cohen, MD, Chief of the Division of Cardiology, and interventional cardiologist Madhu Salvaji, DO. The device was implanted to provide cardiac support during a high-risk angioplasty. "The patient had considerable myocardial ischemia resulting from prior heart attacks and two complete coronary blockages. Her ejection fraction was 15 percent," said Dr. Cohen. "Because her blood pressure was stronger and heart function showed improvement right away, we were able to remove the Impella immediately following the procedure."

For more information about the comprehensive VAD program at the Saint Barnabas Heart Center at Newark Beth Israel Medical Center, please call 1.888.8.HEART.1 or 1.888.843.2781.

If you would like to receive subsequent issues of The Cardiovascular News Beat via email, please submit your email address to cvinformatics@sbhcs.com.

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AMERICA'S BEST HOSPITALS 2009-2010

U.S. News & World Report ranks Newark Beth Israel Medical Center among the nation's top 50 hospitals for specialty care in Heart and Heart Surgery.

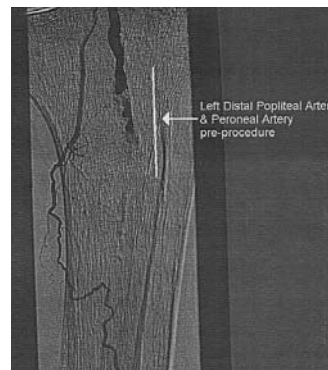


WOMEN'S CARDIAC RISK ASSESSMENT

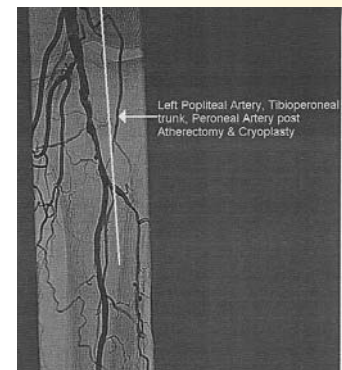
Saint Barnabas Medical Center (SBMC) and the Ambulatory Care Center (ACC) are piloting a new Women's Cardiac Risk Assessment that brings this important health screening to women in settings where they can easily access it. "The program is based on the American Heart Association's Evidence-based Guidelines for Cardiovascular Disease Prevention in Women, 2007 Update," said Gary J. Rogal, MD, Chief of Cardiology for the Saint Barnabas Health Care System. *continued on next page*

USE OF POLAR CATH HELPS PATIENT AVOID AMPUTATION

Madhu Salvaji, DO, used Newark Beth Israel Medical Center's new PolarCath system to return circulation in an 81-year-old patient's leg and help her avoid amputation. The PolarCath combines angioplasty and cold therapy to open arteries and help prevent future blockages in the same location. Dr. Salvaji opened three blockages using a combination of cold catheter, stent placement and atherectomy.



Before PolarCath



After PolarCath

**SAINT BARNABAS
HEART CENTERS**

New Jersey's Health Care Leader

Women's Cardiac continued

"Women understand intellectually that heart disease is the number one killer, but they don't personalize the statistic," explained Janie Baranyay, APN, Quality Cardiac Coordinator at SBMC. "Many still have not had a discussion about heart disease with a primary care physician." The new screening survey, designed specifically for women by researchers at Stanford University, empowers women to begin that discussion and start on the pathway of preventative care.

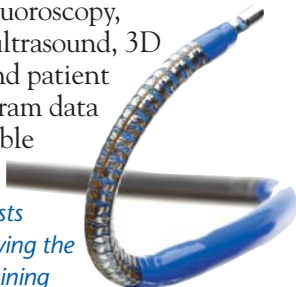
Cardiologists are partnering with other disciplines, such as Ob/Gyn, radiology and oncology to promote risk assessment when women are receiving other annual health screenings such as Pap smears and mammograms. The 19-question assessment will also be available on the Heart Centers' web site later this year. Women at risk will be encouraged to make an appointment with a cardiac nurse practitioner at the Saint Barnabas Ambulatory Care Center. Based on the results, they will be referred to an internist or cardiologist for management of their cardiac health.

In addition to screening, testing and referral, the program includes scheduled follow-up that will track the program's impact on heart disease prevention.

ROBOTIC CATHETER

The first robotic-assisted ablation was performed at SBMC last month by David Dobesh, MD. SBMC is among the first hospitals in New Jersey to provide robotic catheter and navigation technology that incorporates fluoroscopy, intra-cardiac ultrasound, 3D surface map and patient electrocardiogram data into one portable workstation.

Electrophysiologists interested in viewing the technology or gaining certification are invited to contact Saint Barnabas Medical Center at 973.322.9908.



CARDIOVASCULAR RESEARCH

The prominent cardiovascular research conducted at the Heart Center at Newark Beth Israel Medical Center helps patients gain access to promising new treatments and technologies. Our researchers participate in industry sponsored and investigator initiated clinical trials that encompass general and interventional cardiology, electrophysiology, heart failure, heart transplant, cardiac surgery and ventricular assist devices. The entire team works closely to incorporate research findings into the comprehensive care to improve patient outcomes.

Newark Beth Israel remains one of the leading enrolling centers for the nationwide HeartMate II LVAS trial that is evaluating the device as a bridge to transplant and as destination therapy. The results of the TIC-TAC trial initiated by David Baran, MD, Director of Heart Failure and Transplant Research, is making news world-wide regarding immunosuppressive therapy in heart transplant recipients.

CURRENTLY ENROLLING TRIALS

ACORN GEN-2 Clinical evaluation of cardiac support device: a feasibility trial protocol; Principal Investigator: Margarita Camacho, MD

ACORN-MVR Clinical evaluation of Acorn Cardiac Support Device Therapy in patients with dilated cardiomyopathy—A confirmatory trial; Principal Investigator: Margarita Camacho, MD

ASCEND-HF Double-blind, placebo-controlled, multi-center acute study of clinical effectiveness of Nesiritide in subjects with decompensated heart failure; Principal Investigator: David Baran, MD

ATOLL STUDY Acute STEMI treated with primary angioplasty and intravenous enoxaparin or unfractionated heparin to lower ischemia and bleeding events at short and long-term follow-up; Principal Investigator: Marc Cohen, MD

CRISP AMI Multi-center, randomized, controlled study of mechanical left ventricular unloading with counterpulsation to reduce infarct size pre-PCI for acute myocardial infarction; Principal Investigator: Marc Cohen, MD

CTOT-05 Observational study of alloimmunity in cardiac transplant from the time of transplant to one-year post-transplant; Principal Investigator: David Baran, MD

DURAHEART LVAS Evaluation of the safety and effectiveness the Duraheart Left Ventricular Assist System in patients awaiting heart transplantation; Principal Investigator: Margarita Camacho, MD

HEARTMATE II LVAS Evaluation of the HeartMate II Left Ventricular Assist System as destination therapy versus the HeartMate XVE System; Principal Investigator: Margarita Camacho, MD

IMAGE Invasive Monitoring Attenuation Through Gene Expression Trial; Principal Investigator: David Baran, MD

MARVEL Phase II/III, double-blind, randomized, controlled, multi-center study to assess the safety and cardiovascular effects of MYOCELL implantation by a catheter delivery system in congestive heart failure patients post myocardial infarction(s); trial is temporarily on hold waiting for a protocol amendment from the FDA; Principal Investigator: Mark J. Zucker, MD, JD

UPCOMING TRIALS

CVBT—Human recombinant fibroblast growth factor-1 (FGF-1141) for the treatment of subjects with severe coronary heart disease, a double-blind, placebo-controlled, dose-varying study; Principal Investigator: Mark J. Zucker, MD, JD

REG1_CLIN211 Randomized, partially-blinded, multi-center, active-controlled, dose-ranging study assessing the safety, efficacy and pharmacodynamics of REG1 Anticoagulation System compared to unfractionated Heparin or low molecular Heparin in subjects with acute coronary syndrome; Principal Investigator: Marc Cohen, MD

To learn more about the clinical trials conducted at NBIMC please call the cardiac research team at 973.926.8541.