HEARTLINE
Autumn 2007

Montefiore-Einstein Heart Center | MONTEFIORE
The University Hospital for the Albert Einstein College of Medicine

One of Seven Prestigious NIH Grants Awarded to MEHC

Researchers at the Albert Einstein College of Medicine and the Montefiore-Einstein Heart Center have received a 5 year grant from the National Institutes of Health (NIH) to conduct pioneering studies in cardiovascular disease management.

Only seven heart centers in the United States and Canada were selected to participate in this landmark study of evidence-based medicine in cardiothoracic surgical practice. Other grantees are: the Cleveland Clinic; Duke Medical Center, the University of Virginia; Emory and Columbia Universities; and the Montreal Heart Institute.

Robert E. Michler, M.D., the principal investigator for the grant, is Professor and Chairman of Cardiothoracic Surgery at Einstein and Montefiore, Co-director of the Montefiore-Einstein Heart Center, and the Samuel I. Belkin Professor at Einstein.

"This five-year NIH Network grant has the potential to dramatically improve the treatment of cardiovascular disease, still the leading cause of death in the United States and Canada," said Allen M. Spiegel, M.D., The Marilyn and Stanley M. Katz Dean at Einstein. "We are gratified to be a part of this award and these important studies."

Elizabeth G. Nabel, M.D., Director of the National Heart, Lung, and Blood Institute of the National Institutes of Health commented, "By enhancing the ability of research teams to evaluate new techniques, technologies, and devices, the Network promises to improve the scientific basis of care in cardiovascular disease."

The seven participating institutions will collaborate closely during the five-year period to improve technologies used in treating cardiovascular disease, and will meet regularly throughout the year to exchange data and compare findings. "Our participation in this innovative collaboration among leading U.S. and Canadian heart centers, places the Montefiore-Einstein Heart Center at the forefront of cutting-edge cardiovascular research. It is our hope and expectation that this study will lead to significant improvements in cardiovascular disease outcomes for patients," said Dr. Michler.

Additional researchers from Albert Einstein College of Medicine and the Montefiore-Einstein Heart Center who will participate in the study include:

Daniel Goldstein, M.D.; David D'Alessandro, M.D.; Ricardo Bello, M.D./Ph.D.; Simon Maybaum, M.D.; V.S. Srinivas, M.D.; Roger Swayze, R.N.; Hillel Cohen, Ph.D.; Richard Kitsis, M.D.; Linda Haramati, M.D.; and Daniel Spevak, M.D.

Also in this Issue:

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Co-Directors:
Richard N. Kitsis, M.D.
Dorros Chair
Professor and Chief
Division of Cardiology

Robert E. Michler, M.D.
Belkin Chair
Professor and Chairman
Department of
Cardiothoracic Surgery

Heartline Editors:
Chris Snyder
Melissa Crissman

Correspondence:
Marketing Department
111 East 210th Street
New York, NY
10467-2490

tel. 718 920 7823
fax 718 405 1938

Robotics Expert Joins Montefiore-Einstein Heart Center

Dr. Joseph A. DeRose, Jr., is one of the newest members of the "dream team" of surgeons assembled by Dr. Robert E. Michler, Chairman of the Department of Cardiothoracic Surgery at the Montefiore-Einstein Heart Center. Dr. DeRose joined Montefiore-Einstein Heart Center in December 2006 as the Director of Minimally Invasive and Robotic Cardiac Surgery and Associate Professor of Cardiothoracic Surgery at the Albert Einstein College of Medicine.

"Robot-assisted surgery is one of the latest innovations in heart surgery and we welcome the addition of Dr. DeRose, one of the true pioneers and experts in this young field," said Dr. Michler. "This approach also has the potential to benefit thousands of patients every year who may have no other options for treatment. Robotic procedures can result in less trauma and shorter recoveries," added Dr. Michler.

Dr. DeRose earned his medical degree from Columbia University College of Physicians and Surgeons and completed his surgical residency and cardiothoracic fellowship at Columbia-Presbyterian Medical Center. He pioneered the cardiac application of the da Vinci Surgical Robot™, performing the first robotic biventricular pacemaker in the world in 2002. He likewise participated in the first robotic atrial septal defect closure in the United States and the first robotic thymectomy in the United States for Myasthenia Gravis.

After completing an advanced fellowship in minimally invasive and robotic surgery, Dr. DeRose served as the Director of Robotics at St. Lukes-Roosevelt Hospital until joining the Montefiore-Einstein Heart Center cardiothoracic team in 2006.

At Montefiore, Dr. DeRose and other surgeons use Intuitive Surgical's daVinci. "Robot-assisted procedures allow access to the heart with three small holes made between the ribs through which two robotic arms and a miniature camera are inserted, avoiding the need for opening the chest," explains Dr. DeRose. "This allows patients faster recuperation and full recovery in less time than before."

Like many innovations and procedures at the Montefiore-Einstein Heart Center, robotic-assisted surgery brings to fruition a vision that once existed merely in the realm of science fiction and within a few forward-thinking minds. "It has been a major advance in the approach to open heart surgery, and having someone of Dr. DeRose's caliber, who has had a great deal of experience in heart surgery with this equipment, will greatly benefit our cardiothoracic surgery program and our patients," says Dr. Michler.

"This approach also has the potential to benefit thousands of patients every year who may have no other options for treatment."

Promising Medication for Heart Failure Studied

A research team headed by Simon Maybaum, M.D., of the Montefiore-Einstein Heart Center, says that the asthma medication, Clenbuterol, might help heart failure patients stay strong without the need for a heart transplant. The first U.S. study of the medication found it was safe in a small number of study participants with heart failure. The medication was also found to increase skeletal muscle mass and strength, although there was no significant change in heart function. Dr. Maybaum was lead author of the study, which was presented last spring at a meeting of the International Society of Heart and Lung Transplantation in Madrid, Spain.

Richard N. Kitsis, M.D. (left) and Robert E. Michler, M.D. (right), Co-Directors of the Montefiore-Einstein Heart Center.

The trial is an example of how far physicians will go to find solutions to the growing problem of heart failure. While the end step for many heart failure patients is a heart transplant, the worldwide shortage of organ donors leaves many patients on heart pumps in order to survive. "The idea is to one day develop strategies to promote cardiac recovery while patients are supported with a heart pump. That would obviate the need for heart transplants," says Dr. Simon Maybaum, Co-Director of the Center for Advanced Cardiac Therapy and the Cardiac Transplant and Assist Device Program. "This is a growing area of research, and both novel pharmacological agents and cellular therapy [stem cells] will be studied. This research is crucial because of the critical lack of organs for patients with end-stage heart failure."

Excerpts taken from Journal of the American Heart Association, Spring 2007

▶ *Thirteen/WNET New York presents* ***The Mysterious Human Heart****, a new PBS series from filmmaker David Grubin that explores the body's perpetual motion machine and how we cope with coronary diseases, to premiere October 15, 2007.*

Three-part series is co-production of David Grubin Productions, and Thirteen/WNET New York in association with WETA Washington, D.C.

See Montefiore-Einstein Heart Center Featured This Fall

HEART CENTER CAMPAIGN	September 2007					October 2007					November 2007		
Weeks of	8/27	9/3	9/10	9/17	9/24	10/1	10/8	10/15	10/22	10/29	11/5	11/12	11/19
Television/Cable (30 second commercials)				■	■	■			■	■	■		
Radio (60 second commercials)				■	■	■			■	■	■		
Local Magazines													
New York Magazine		■	■						■				
Editorial	"Fall Preview Double Issue"							"Heathcare Issue"					
Westchester Magazine	■	■	■	■	■					■	■	■	■
Editorial	"Fall Preview Guide"									"Top Docs Issue"			

BIO-ETHICS

by Hannah Lipman, M.D.

Bio-ethics is the study of morality and conduct in medicine and health care. Clinical medical ethics brings this philosophical academic discipline to the bedside. The field of clinical medical ethics has grown in recent decades for many reasons, including the JCAHO requirement that each health care organization have a process in place to respond to ethical issues as they arise. Public awareness of the ethical issues in health care has risen due to national attention to prominent end of life cases such as those of Karen Ann Quinlan in the 1970s, Nancy Cruzan in the 1980s and Terri Schiavo in 2005. Additionally, increasing attention has been paid to problems of health care access and appropriate use of advanced technologies in the lay press, notably the recent New York Times front page article about Dr. Michael E. Debakey undergoing aortic surgery at age 97.[1]

Those famous cases grabbed national attention, but ethical dilemmas arise in the practice of medicine every day. Conflict occurs when the obligations and responsibilities of the physician or health care professional support two opposing actions in a given situation. Resolving these dilemmas requires the same sort of systematic reasoning we apply when examining medical uncertainties. This process often requires a careful analysis of the benefits and burdens of proposed options, the goals and interests of the patient and family, and the ethical and regulatory context of the case.

Concepts in medical ethics are often reduced to the basic principles of beneficence, the obligation to benefit patients to further their welfare and interests; nonmaleficence, the obligation to prevent harm and minimize risks; autonomy, the obligation to protect and defend the informed choices of capable patients; and justice, the obligation to promote fairness in access to and distribution of health care resources across society. These basic principles may aid clarification of the issues in a case, but often the problem is more nuanced. Reframing ethical dilemmas by examining the interests of the involved parties, including not only the needs and interests of the patient, but also of the surrogate decision makers, other family, the physician and the institution as well as the social and medical context of the situation gives a richer sense of the problem in a case.[2]

(Continued on p6)

Cardiology Grand Rounds Schedule

Jack D. Weiler Hospital, Weiler Auditorium

Sept. 11	8 am – 9 am *Advances in Imaging in Coronary Artery Disease: A Multimodality Approach* Dr. George A. Beller
Sept. 18	8 am – 9 am *Pulmonary Arterial Hypertension: A Medical Update* Dr. Erica B. Rosenzweig
Sept. 25	8 am – 9 am *Lipid Interaction on Insulin Secretion — Is There A Human Paradox* Dr. Daniel T. Stein

Cardiothoracic Surgery Grand Rounds Schedule

Greene Medical Arts Pavilion, 7th Floor Conference Room

Sept. 10	8 am – 9 am *Interesting Case Presentations*
Sept. 17	8 am – 9 am *Journal Club*
Oct. 1	8 am – 9 am *Surgery for Ischemic Mitral Valve Disease* Dr. Dave D'Alessandro
Oct. 8	8 am – 9 am *Interesting Case Presentations*
Oct. 22	8 am – 9 am *Journal Club*
Oct. 29	8 am – 9 am *Acute and Chronic Pain Management* Sandra Goodman, N.P.

Effectiveness of Glycoprotein IIb/IIIa Inhibitor Use During Primary Coronary Angioplasty: Results of Propensity Analysis Using the New York State Percutaneous Coronary Intervention Reporting System

Vankeepuram S. Srinivas MBBS, Basel Skeif M.D., Abdissa Negassa PhD, Ji Yon Bang MS, Hussein Shaqra M.D. and E. Scott Monrad M.D.

Patients undergoing primary angioplasty in clinical practice experience a higher risk for adverse events than those enrolled in clinical trials. Whether glycoprotein (GP) IIb/IIIa inhibitor use during primary angioplasty is both safe and effective in real life is unknown. Therefore, we examined the pattern of GP IIb/IIIa use and its effectiveness in a large population-based cohort of 7,321 patients who underwent primary angioplasty in New York State. Propensity analysis was used to account for the nonrandomized use of GP IIb/IIIa inhibitors. Overall, 78.5% of patients who underwent primary angioplasty received GP IIb/IIIa inhibitors. In-hospital mortality was significantly lower with GP IIb/IIIa use (3% vs 6.2%, p <0.0001) after adjustment for both propensity score (odds ratio 0.57, 95% confidence interval 0.44 to 0.74, p <0.0001) and the combination of propensity score and clinical characteristics (odds ratio 0.63, 95% confidence interval 0.45 to 0.88, p = 0.006). Patients with older age and higher Mayo Clinic Risk Score (MCRS) received GP IIb/IIIa inhibitors less often. However, stratified analysis of patients with low to moderate risk (MCRS <12) versus high risk (_12) demonstrated that GP IIb/IIIa use lowered risk of mortality both in low- to moderate-risk (1.39% vs 3.23%, p <0.0001) and high-risk patients (16.15% vs 22.41%, p = 0.03). In conclusion, adjunct GP IIb/IIIa inhibitor use during primary angioplasty is effective and associated with improved in-hospital survival rates.

Pulmonary Arterial Hypertension Clinical Trial

Pulmonary Arterial Hypertension (PAH) is a frequent secondary condition seen in patients with cardiac disorders. There are a few FDA approved agents for PAH, however, significant morbidity and mortality still exists. The mechanisms promoting this condition are complex and many drugs are being investigated for therapeutic potential. One mechanism thought to play a role in PAH is the release of Enothelin-1, a powerful endogenous vasoconstrictor. Tezosentan is an investigational intravenous drug that blocks Endothelin receptors. Montefiore-Einstein Heart Center is participating in an international, multi-center, double-blind, randomized, Phase III clinical trial that is assessing the potential benefit of Tezosentan compared with placebo in the treatment of patients with pre-operative PAH undergoing open heart surgery with cardiopulmonary bypass. Treatment time is from the start of surgery up to 24 hours post-operative.

The Montefiore-Einstein Heart Center enrolled the very first patient in this trial and leads enrollment worldwide. This commitment to investigate new therapies distinguishes Montefiore-Einstein Heart Center as a leader in the future of cardiac care.

MONTEFIORE
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The University Hospital for the Albert Einstein College of Medicine
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Marketing Department
111 East 210th Street
New York, NY 10467-2490

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Bio-Ethics *(continued from p4)*

"Examination of real clinical cases is the most interesting and straightforward way of learning how to bring relevant medical ethical principles to bear in our medical practice."

It is not surprising that many ethical dilemmas arise particularly in the practice of cardiology. Issues of delivering emergency life saving care, taking care of the aging population, providing compassionate care at the end of life, ensuring appropriate distribution of scarce resources, developing new technologies, and doing state of the art research all converge in the care we provide to cardiac patients.

Examination of real clinical cases is the most interesting and straightforward way of learning how to bring relevant medical ethical principles to bear in our medical practice. As a Geriatric Cardiologist, many cases of interest to me involve the basic question of how to apply data from the evidence base, which usually excludes older adults with multiple chronic problems, to each patient in an individualized way. Common issues include assessment of decision making capacity, informed consent and refusal, accurate prognostication, planning for end-of-life, appropriate use of advanced technologies such as ICDs and LVADs, and appropriate use of scarce resources, such as CCU beds.

Fundamentally, however, medical ethics is about patients' stories. At Montefiore, there is a Bio-Ethics Consultation Service comprised of professionals expert in ethical analysis of complex cases or cases in which the optimal plan of care is uncertain. Of course, not every case requires expert consultation, but the advice and education such a service provides in assisting clinicians to apply a systematic ethical analysis to sort out the patients' stories in order to achieve the best possible outcome is invaluable. The goal of ongoing conversation about these issues is to make the concepts of medical ethics accessible, relevant, interesting, and applicable to our patient care practice and therefore improve the care of our patients, work towards improvement of our health care delivery system, and increase professional satisfaction.

Dr. Hannah Lipman *is Assistant Professor of Medicine in the Department of Medicine, Divisions of Geriatrics and Cardiology, at the Montefiore Medical Center, Albert Einstein College of Medicine, where she is involved in education in medical ethics with an emphasis on end-of-life care in cardiac patients.*

1. Altman, Lawrence K. "The Man on the Table Devised the Surgery." New York Times. December 25, 2006.

2. See Lipman, HI. Ethical Issues in the Management of Geriatric Cardiac Patients. American Journal of Geriatric Cardiology. 2006; 15(6):279-81. from which parts of this article were excerpted.