



Dr. Andrew D. Michaels Appointed IEPR Medical Director

Andrew D. Michaels, MD, FACC, FAHA

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Dr. Andrew D. Michaels is Assistant Professor of Medicine and Co-Director of the Adult Cardiac Catheterization Laboratory at the University of California-San Francisco Medical Center. A Harvard College graduate with degrees in history and science, Dr. Michaels received his medical degree from the University of California-San Francisco, continuing there to complete his internship and residency in internal medicine and his cardiology and interventional cardiology fellowships.

Dr. Michaels has a long history as an EEC thought leader and lecturer, and as a participant in the IEPR Working Group. Providing EEC at the UCSF Refractory Angina Clinic during his cardiology fellowship in 1996 was Dr. Michaels’ first exposure to EEC and the beginning of his participation in the IEPR Working Group which continued after joining the UCSF faculty in 2000, and with which he remains actively involved to the present. Of 35 original manuscripts, review articles, book chapters, and books to date, Dr. Michaels has published six original manuscripts on EEC from registry data and other clinical investigations.



A five-year *National Institute of Health Mentored Patient-Oriented Research Career Development Award* affords Dr. Michaels the exciting opportunity to study the hemodynamic and clinical effects of EEC in patients with acute coronary syndrome. Extensive patient care and research interests also include refractory angina, coronary revascularization (angioplasty, atherectomy, and stenting), valvuloplasty, coronary hemodynamics, and interventional techniques for congenital heart disease, including patent foramen ovale (PFO) and atrial septal defect (ASD) closure.

As newly appointed Medical Director of the IEPR and Chair of the IEPR Manuscript Writing Group, Dr. Michaels, “welcomes the opportunity to continue working with the IEPR sites, statisticians, and Manuscript Writing Group, to further advance the understanding of the mechanisms of action and effects of EEC.”

IEPR

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IEPR

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Recent Publications:

Michaels AD, Linnemeier G, Soran O, Kennard ED: Two-Year Outcomes After Enhanced External Counterpulsation for Stable Angina Pectoris (from the International EECPP Patient Registry [IEPR]). *American Journal of Cardiology* 2004;93:461-464.

Recent Presentations:

American College of Cardiology, New Orleans, LA, March 2004

Marked Underutilization and Geographic Variation in Secondary Prevention Pharmacologic Therapy in Patients with Chronic Angina Undergoing Treatment with EECPP

A Michaels

Treatment Hours and Angina Improvement with EECPP

W Lawson

Enhanced External Counterpulsation Improves Functional Capacity and Quality of Life in Women with Chronic Angina

G Linnemeier

Frequency and Results of Repeat Enhanced External Counterpulsation for Refractory Angina

W Lawson

In addition to the abstracts based on Registry data, EECPP was featured in four "Meet the Experts" sessions, and four oral presentations discussing the effect of EECPP therapy on wave reflection amplitude, microvascular angina, electrophysiologic remodeling, and myocardial perfusion.

Society for Cardiovascular Angiography and Intervention (SCAI), 27th Annual Scientific Sessions, San Diego, CA, April 2004

Comparison of Clinical Outcomes, Event Free Survival Rates in Patients with Severe Left Ventricular Dysfunction Undergoing Enhanced External Counterpulsation and Percutaneous Coronary Intervention for Angina Pectoris

O Soran, ED Kennard, F Seltzer, H Cohen

For complete bibliographies visit:

the IEPR website: www.edc.gsph.pitt.edu/iepr/

the Vasomedical website: www.eecp.com

Form Compliance

IEPR-1

Six Months:	97%
One Year:	97%
Two Years:	96%
Three Years:	92%

INTERNATIONAL

Six Months:	87%
One Year:	88%
Two Years:	79%
Three Years:	71%

IEPR-2

Pre-EECPP:	98%
Post-EECPP:	100%
Six Months:	98%
One Year:	99%
Two Years:	100%

IEPR CONTEST WINNERS:

Diabetes Contest Winner

University Medical Center
of Stony Brook,
Stony Brook, NY
William Lawson, MD
Denise D'Ambrosia, FNP-C

Special thanks and appreciation to:

Mary Cassidy, RNP
The Cardiovascular Specialists, LLC
Falmouth, MA

Dr. Huan Loh
Hull Royal Infirmary
East Yorkshire, UK

for making the extra effort to bring their IEPR data up to date.

Complete Patient Follow-up – The IEPR Coordinators’ Challenge

Sheryl Kelsey, PhD, Director of the Registry Coordinating Center for IEPR

As recruitment for IEPR Phase 2 approaches completion, Registry coordinators and investigators can enjoy a feeling of gratification at having contributed to the collection of data for 2500 patients treated with EECP. The Registry now enters the important, and in some ways, more challenging phase, that of long-term follow-up. Throughout the course of their participation, the coordinators have been contacting the enrolled patients by telephone or catching up during a scheduled office visit. But keeping in touch with all the patients can become more of a challenge as the time since the course of therapy grows longer. Complete follow-up is, however, the key to long-term evaluation of the therapy. As EECP gains more and more attention, the question of how long the benefits last is heard more and more often.

In addition to answering questions about duration of benefit, follow-up information will be used to examine many other issues, such as, do some groups of patients do particularly well with EECP? We have found that women in the Registry have poorer functional status than men. Does this differential persist? Under what circumstances do patients have repeat EECP? Is there a difference in the response to an additional course of therapy?

The Registry can answer these crucial questions, but only if we have unbiased data. If we do not have complete follow-up, we cannot be sure that the patients are representative of all patients who undergo EECP. Bias can creep in if the patients who are not contacted are patients who are doing really well or really poorly. Patients who do not feel well may be reluctant to talk on the telephone. Patients who are feeling well may be off on a vacation or wintering in Florida.

Ultimately, the goal is to present registry data at national and international clinical meetings, and to publish manuscripts in peer-reviewed medical journals to reach a wide audience of cardiologists, internists, family practitioners, endocrinologists and gerontologists. Leading journals demand sound data with complete follow-up information on all patients. The role of the IEPR coordinator is key in meeting this challenge – insuring the validity of these data.

We recognize that follow-up is not always easy, and we know that reaching the patient by telephone can actually be the most challenging part. Tips from successful coordinators include verifying contact information (winter and summer residences), and asking for friends and family members who would know how, when and where to reach the patient. Telephoning on the weekends and

evenings may be required to reach some patients, particularly if they are still employed. Once the patient is on the phone, eliciting the necessary information generally goes smoothly. Of course, there are those patients who like to talk and the interview goes longer than you hoped.

Appealing to the patient’s altruism may prove to be effective – a reminder that participation in the Registry will help future patients. Since heart disease usually runs in families, the knowledge gained from the Registry may serve to improve the future health and well-being of children and grandchildren.

Keeping a file of some personal information about the patient, e.g. asking about grandchildren, a recent vacation trip, or a family wedding or major anniversary can help make the follow-up contacts friendlier and more personal. Successful coordinators find that holiday and birthday cards are welcome gestures and help to keep the Registry on the minds of the patients. It is not unusual for patients to forget that they are part of a research study. At the end of the call, thanking the patient for his/her time and information, reminding the patient that you will be calling next year, and wishing him/her a happy and healthy year can leave the patient with a positive feeling and a sense of participating in something important. Finding out about patients who have died may take some extra detective work. Checking newspaper obituaries or the National Death Registry can be helpful.

On a personal note, I found that it was useful for me as a researcher to be a participant in a clinical trial and experience the other point of view. I have never had EECP, but I am enrolled in a National Cancer Institute-sponsored clinical trial, PCLO (Prostate, Colon, Lung, Ovarian), that screens for cancer. I was randomized to the control group so am not undergoing tests as part of the trial, but there is still annual follow-up for sixteen (16!) years. The birthday card from the study coordinator is always a pleasant surprise and a friendly reminder that I am an active participant in an ongoing clinical trial. Randomization to the control group allows it to slip from awareness; then suddenly the time for the annual follow-up arrives again. The surprise is not the study participation but how quickly the time has passed.

Be assured that your diligence with thorough follow-up will be rewarded – you (and your patients) are making a significant contribution to the knowledge of how EECP can help patients suffering with coronary artery disease and heart failure.



IEPR Site Spotlight:

Hennepin County Medical Center, Minneapolis, MN

Bradley Bart, MD, Medical Director • Kim Jusuola, MA, EPC • Matt Sigafus, EP • Lisa Smyrak, Billing Consultant

The EECP program at Hennepin County Medical Center was the first fully independent EECP program in Minnesota. We have continuously provided services for our patients and those referred from our colleagues around the state since 2000.

Hennepin County Medical Center is a tertiary care level I trauma center in downtown Minneapolis. It is the main teaching hospital for the University of Minnesota School of Medicine and has its own internal medicine residency. One of the primary missions of the hospital is to provide care for the underserved population living in Hennepin County.

We knew there was a clinical need for EECP because of our research experience with angiogenesis growth factors (VEGF and FGF) in the late 1990's. These trials were recruiting patients with advanced angina and coronary artery disease not amenable to standard revascularization – the perfect EECP patient! While recruiting for these trials, we realized that there were a lot of these “no option” patients in the community. The results of the angiogenesis trials were mostly neutral and to this day, these compounds are not available to patients outside research protocols. However, EECP remains a clinically effective, non-invasive and safe treatment for the “no option” patient.

Personally, I first learned about EECP while trying to find a treatment option for my grandfather. He was 84 at the time, had undergone

bypass surgery twice in the past and had class IV angina. Eating a large meal was enough to give him chest pain and he was on maximum medical therapy. I read an article about EECP and was interested in referring my grandfather for treatment, but found that there were no EECP centers in Minnesota at the time. One thing led to another and we opened our EECP program in 2000; my grandfather was one of the first patients to complete a course of therapy. I am happy to say that he had a remarkable response to treatment. He is now 87 and walks a mile 3 to 4 times a week (slowly)! He does not have any angina and has participated in family weddings, birthdays, graduations and just everyday living.

A teaching hospital is an ideal place for an EECP program. Trainees at all levels are fascinated by the physiology of counterpulsation therapy and the “unconventional” appearance of the equipment. Learning how EECP improves endothelial function, symptoms, treadmill time and ischemic burden offers a perfect model for translational research.

The success of our program is largely due to the quality of our coordinator/therapists. Without them, the program simply could not work. Finding the right people to interact with referring doctors, hospital administrators, nurses and patients is key. We have been very fortunate in this respect and Kim Jusuola deserves a lot of credit for keeping the program alive. Our EECP program is part of the complete range of cardiovascular services that we feel we can offer to our patients and the community.



(from l to r) Dr. Bart, Kim, Matt, Lisa



With Thanks to Dr. Georgiann Linnemeier

Our heartfelt thanks to Dr. Georgiann Linnemeier, who as Medical Director for the last three years has guided the IEPR. During this time Phase 2 of the Registry was designed and implemented and sub-studies on diabetes and mens' health were started. We at the coordinating center particularly benefited from Dr. Linnemeier's dedication to the project. She was always available to us to answer what to her were probably very simple clinical questions, and to give guidance when we were struggling with design questions.

Under Dr. Linnemeier's leadership the Working Group of the IEPR produced ten manuscripts and gave over 40 presentations at both national and international meetings. Dr. Linnemeier's particular interest in the use of EECP for diabetic patients and for the elderly has resulted in 11 oral and poster presentations as well as articles in peer-reviewed journals.

We would like to extend our heartfelt thanks and our very best wishes to Dr. Linnemeier in her new endeavors.



Clinical Tips



Managing the EECP Patient with Back Pain

Patients that suffer with chronic back or arthritic pain, or have had back, hip or knee surgery often challenge the EECP therapist's creativity in the effort to make and keep these patients comfortable throughout the complete course of EECP therapy. A poll of experienced EECP therapists and the Vasomedical Clinical Application Specialists provided the following helpful hints:

- Encourage the patient to take his/her prescribed pain/anti-inflammatory medication about an hour before coming for EECP. If a stronger pain medication seems indicated and the patient does not have a prescription contact the patient's physician.
- Taking a warm shower an hour before treatment may help relax tight muscles.
- Encourage the patients that can to do stretching exercises for the lower back in the morning and evening. The most common is lying on the back, bringing one knee slowly toward the chest, holding for a count of 5-10, then slowly bringing the leg back down to the bed. Repeat with the other leg. Encourage as many reps as possible.
- Proper positioning and wrapping of the treatment cuffs can play an important part in ensuring patient comfort. Positioning the cuffs too low on the hips has been noted to exacerbate lower back discomfort.
- Positioning the patient comfortably on the treatment table is key:
 - o Place a small pillow or rolled towel under the knees.
 - o Provide additional support to the lower back or wherever there is an area of discomfort, i.e. under an arm or shoulder.
 - o Position the patient's upper body to a level that is most comfortable. For some patients that may be low, for others raised. It is best not to assume but to work with the patient until the optimum position is found.



IEPR

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Compliance Champions!

PLATINUM - 99-100%

Mercy Hospital Medical Center
Jackson Purchase Medical Center
Northwest Ohio Cardiology Consultants
William Beaumont Hospital
The Heart Care Group, PC
Wake Heart Associates
Moffitt Heart and Vascular Group
Associates in Cardiovascular Medicine
EECP Center of Pittsburgh
Central Arkansas Cardiology
EECP of Nassau

University of Virginia
University of Pittsburgh Medical Center
Cardiovascular Research Institute, Inc.
Shady Grove Adventist Cardiac Rehab
Consultants in Cardiovascular Disease, Inc.
Mayo Clinic, Saint Mary's Hospital
Christ Hospital and Medical Center
North Suburban Cardiology Group
Staten Island Heart
Shands Hospital
Riverside Regional Medical Center

Cotton O'Neil Heart Center
Our Lady of Lourdes Medical Center
The Heart Group
Oregon Cardiology
Edgardo Bermudez, MD
Creighton University Cardiac Center
Wisconsin Heart
Integrative Cardiology
Independence Cardiology Associates

GOLD - 95-98%

University Medical Center of Stony Brook
Southwest Heart
Griffin Hospital
Indiana Heart Associates, PC
Hennepin County Medical Center
Ochsner Foundation Hospital
Heart Centers of America, LLC
Missouri Heart Center

Susquehanna Cardiology Associates
Cardiovascular Associates of N. Wisconsin
Hammersmith Hospital, UK
Mason City Clinic, Mercy Heart Center
St. Luke's Regional Medical Center
The Angina Center at Ohio Valley Heart
Monmouth Cardiology Associates
Minneapolis Heart Institute Foundation

Cardiovascular Clinic of
Plaza Medical Group
Central Baptist Hospital
Elliott Hospital
EECP Center of Northwest Ohio
Medcor Cardiology
Medical Institute of New Jersey

SILVER - 90-94%

Lyford Cay Hospital
Advanced Heart Care
Knoxville Cardiovascular Group

Vital Heart Clinics
Cardiovascular Specialists
Avera McKennan Hospital

Medkar Heart Center, Turkey
Aruba Heart Institute and Medical Center