



IEPR Newsletter

EECP® Therapy: Nine Presentations at the ACC!

From the Desk of the IEPR Medical Director

Georgiann Linnemeier, MD
Medical Director, IEPR

The 52nd Annual Scientific Sessions of the American College of Cardiology held in Chicago this spring provided an exciting forum for the presentation of studies on EECP therapy. Nine presentations—including a symposium and a “Meet the Experts” session—were delivered in addition to six reports from IEPR studies.

Two-Year Follow-up & End-Stage Ischemic Heart Disease Data

Six poster presentations displayed a variety of data. Dr. Andrew Michaels *et al* analyzed two-year clinical outcome data on 704 angina patients who underwent EECP therapy. He showed that at two-year follow-up, 78% of patients reported class II, I or no angina, and 59% of patients who reported a reduction in angina after the original EECP course, maintained that angina reduction for two years. (abstract #5, page 5)

Dr. William Lawson *et al* showed that patients previously treated with PCI or CABG experi-

enced similar treatment success and durability of benefit with similar event rates and mortality, after treatment with EECP therapy. Although CABG patients are older with more extensive coronary artery disease, heart failure, prior infarcts and severe angina, EECP retains its effectiveness when used as a treatment of last resort for angina. (abstract #1, page 4)

Data: Diabetes & Co-Morbid Conditions

I, along with my colleagues from the University of Pittsburgh, presented studies based upon IEPR data. We demonstrated EECP therapy’s emergence as a viable therapy for patients whose disease progression has rendered them beyond the benefit of invasive and noninvasive intervention. In particular, despite more co-morbidity, it was demonstrated that diabetic and elderly patients (≥ 75 years) were able to derive a durable benefit from EECP treatment. (abstract #2, page 4)

The first of two presentations on diabetic patients showed that in a population of 665 patients undergoing EECP therapy, 69%

had experienced Canadian Cardiovascular Society (CCS) angina class reduction of at least one class. This response was maintained at one-year follow-up with 71.5% reporting maintenance of angina reduction. However, as expected, during the follow-up period, this patient group had higher rates of congestive heart failure, death and cardiac hospitalization. The second presentation delivered data pertaining to diabetic patients diagnosed with severe angina who were not candidates for revascularization. Upon completion of EECP treatment, 83% reported class II, I or no angina, a reduction maintained in 74% of patients. (abstract #4, page 4)

Elderly Patients

Data on elderly patients at high-risk for morbidity and mortality associated with invasive coronary interventions were also

Patients previously treated with PCI or CABG experienced similar treatment success and durability of benefit, with similar event rates and mortality, after treatment with EECP therapy.

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SITE SPOTLIGHT:

William Beaumont Hospital Royal Oak, MI

Anthony Ochoa, MD
Peter McCullough, MD, MPH
Dianna Grayson, RRT

William Beaumont Hospital is a large, non-profit, community hospital located in Royal Oak, Michigan, a suburb of Detroit. Beaumont has been recognized as a leader in many areas of medicine, but is probably best known for its contributions to interventional cardiology. Despite its “invasive” cardiology reputation, Beaumont has embraced EECF therapy, and has recently established a clinical EECF treatment program. William Beaumont Hospital has been offering therapy as well as conducting research with EECF for just over one year. The EECF Treatment Center is located within the Cardiac Rehabilitation and Exercise Testing Area in the newly constructed Beaumont Health Center, just a few miles from the main hospital campus.

The clinical and research EECF programs at Beaumont initially developed from research interests in EECF. Research protocols, supported by grants from Vasomedical Inc. (Westbury, NY), began enrolling patients in April 2002. EECF therapy has since gained wide acceptance among the cardiology staff at Beaumont, which is a tribute to the high success rate achieved with EECF therapy despite many of the patients having previously received laser TMR, gene therapy and biventricular pacing. The number of patient referrals increased

such that the small EECF research staff could not keep up with the volume and a large waiting list evolved. The hospital administration, which had been very supportive of EECF research, approved the creation of a formal clinical EECF treatment program including two additional personnel, and approved the purchase of an additional EECF system for the treatment of outpatients.

We currently have two TS3 EECF treatment systems, which are used for inpatient and outpatient applications. The TS3, dedicated to inpatient use is located in our Coronary Intensive Care Unit, and its primary use is for the research protocol, “The Hemodynamic Effects of EECF in Right Ventricular Acute MI.” We have also used this device in hospitalized patients to treat refractory unstable angina and congestive heart failure. One of our most memorable patient anecdotes is that of a patient who was referred for EECF therapy after being admitted for recurrent unstable angina. Cardiac catheterization was performed and revealed severe coronary artery disease, however, the patient was not a suitable candidate for percutaneous or surgical revascularization. The patient failed to be weaned from intravenous heparin and nitroglycerine on three attempts for rebound unstable angina, and the EECF team was consulted. EECF therapy was initiated on the fourth day after cardiac catheterization, and after several treatment sessions the patient was weaned off intravenous heparin and nitroglycerine and was discharged home. The patient continued on EECF therapy as

an outpatient, and for the first few weeks continued to clutch her nitroglycerine tablet bottle in her hand at all times. However, after completing 35 hours of EECF, the patient was free of angina and had a marked improvement in functional capacity. The patient still carries her nitroglycerine tablet bottle, but now carries it in her purse. She recently visited her cardiologist and is continuing to do well two months after completing EECF.

We have a small, but very dedicated EECF staff. Our goal has been to provide optimal EECF therapy balanced with patient comfort. Patients may listen to music CDs or watch movies while receiving therapy, though their favorite activity remains conversing with the staff. We feel that having a highly motivating and attentive staff is critical to providing effective therapy while maintaining patient compliance and comfort. Dianna Grayson, RRT, our EECF Coordinator (research and clinical) and senior EECF therapist, has recently trained two other cardiac rehabilitation staff members (Anne Davis and Liberty Van Eik) to provide EECF therapy. These three EECF therapists receive constant praise from the patients who complete the EECF program. The location of the EECF Treatment Center in the Cardiac Rehabilitation Area is ideal as exercise physiologists generally have the supportive attitude needed for EECF patients. In addition, our Electrophysiology Clinic is located adjacent to the EECF Treatment Center, and is capable of assisting with pacemaker





The William Beaumont EECOP Staff (Left to Right): Liberty Van Eik, BS, Anthony Ochoa, MD, Dianna Grayson, RRT, Anne Davis, RN and Peter McCullough, MD

programming (turn off rate adaptive mode) as needed before and after each treatment session. Dr. Barry Franklin, Director of Cardiac Rehabilitation and Exercise Testing, and his staff have welcomed this technology in their department, and have plans to further expand the clinical EECOP treatment program and pursue EECOP research.

Our clinical and research EECOP programs are undergoing reorganization with the creation of the formal treatment program mentioned previously. Anthony Ochoa, MD, Chief Clinical Cardiology Fellow at William Beaumont Hospital, initiated the research and treatment programs together with Dianna Grayson. Dr. Ochoa has performed research in

thrombosis/hemostasis, cardio-renal physiology and EECOP, and is a member of the International EECOP Patient Registry (IEPR) Working Group. Dr. Ochoa recently presented the abstract, "Atrial Fibrillation Does Not Degrade the Clinical Benefits from EECOP in Patients with Chronic Angina: Results from the International EECOP Patient Registry," at the American College of Cardiology meeting in Chicago (March 2003). Dr. Ochoa is graduating this June and is departing William Beaumont Hospital to complete a U.S. Air Force active duty commitment and will be assigned to Wright-Patterson Air Force Base in Ohio. Peter McCullough, MD, MPH, will serve as Director of the new Clinical EECOP Treatment Program, and is also a member of the IEPR

Working Group. Dr. McCullough is a former graduate of the William Beaumont Hospital Cardiology fellowship program and has been recruited back to Beaumont after serving as Chief of Cardiology at the University of Missouri, Kansas City. Dr. McCullough currently is the Chief of the Division of Nutrition and Preventive Medicine, and Medical Director of the Preventive Cardiology and Weight Control Center at William Beaumont Hospital. Dr. McCullough has research interests in obesity, cardio-renal physiology and EECOP. In addition to her role as EECOP Coordinator, Dianna Grayson is the IEPR Site Coordinator, and a member of the International EECOP Therapists Association. In addition to providing EECOP therapy and performing the administrative tasks of a research coordinator, Dianna organized the clinical treatment program, and assists in all patient evaluations for EECOP treatment and research.

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presented. The data demonstrated that in a population of 347 Registry patients ≥ 75 years, there was little difference between elderly and younger patients in gender, angina severity or ejection fraction. At one-year follow-up, 81% of patients reported a maintenance of symptom improvement with comparable major adverse cardiac event-free survival in both groups.

EECP therapy helps patients accomplish their goals of living longer and feeling better. This low-risk intervention significantly reduces anginal symptoms with

cardiac event-free survival comparable to younger patients with similar symptoms. (abstract #6, page 5)

Atrial Fibrillation

Dr. Anthony Ochoa *et al* presented data on patients with a history of atrial fibrillation.

At baseline, of the 213 patients studied, 14% were in atrial fibrillation, 22% were paced, 62% were in sinus rhythm and 2% reported "other" rhythms. Patients with a history of atrial fibrillation were older and had a higher incidence of prior myocardial infarction and a history of congestive heart failure. Similar outcome for angina reduction and decrease in nitroglycerin use

was demonstrated in patients with and without a history of atrial fibrillation. (abstract #3, page 4)

I will conclude by applauding all Registry participants. Without the detailed and timely recording of patient demographics, hemodynamics and clinical outcomes "one patient at a time," none of these reports would be possible. Our work broadens the applicability of EECP therapy to patient populations considered too fragile or beyond the benefit of "gold standard" therapies.

A complete IEPR bibliography can be viewed at www.edc.gsph.pitt.edu/iepr

RECENT PRESENTATIONS:

American College of Cardiology 2003 Scientific Sessions March 2003 IEPR

1 Preserved Benefit of Enhanced External Counterpulsation in End-Stage Ischemic Heart Disease

Lawson, Barsness, Kennard, Stony Brook University, Stony Brook, NY, University of Pittsburgh, Pittsburgh, PA

EECP therapy is shown to retain its effectiveness even as a "last resort" therapy. Whether previously treated with PCI or CABG, treatment success, durability of benefit, event rates and mortality are similar in both groups. This effectiveness is retained despite

CABG patients having more extensive coronary artery disease, more prior infarcts, more heart failure, more severe angina and being older than those previously treated with PCI.

2 Is Enhanced External Counterpulsation Effective for Angina Relief in Diabetic Patients Who Are Not Candidates for Transcatheter Intervention?

Linnemeier, Kennard, Soran, Kelsey, University of Pittsburgh, Pittsburgh, PA

PCI in the diabetic patient is problematic. Despite steady improvement in transcatheter interventional techniques and outcomes, there is a growing population of patients who have exhausted the revascularization armamentarium. Novel treatments such as EECP can offer angina reduction with maintenance of benefit for select patients with advanced coronary disease.

3 Atrial Fibrillation Does Not Degrade the Clinical Benefits From Enhanced External Counterpulsation Therapy in Patients With Chronic Angina: Results From the International EECP Patient Registry

Ochoa, O'Neill, Almany, William Beaumont Hospital, Royal Oak, MI

Despite a greater severity of co-morbid states, patients with atrial fibrillation undergoing EECP therapy receive the same clinical benefit as those without atrial fibrillation. Atrial fibrillation does not negatively impact diastolic augmentation during EECP therapy.

4 Enhanced External Counterpulsation for the Relief of Angina in Patients With Diabetes: A One-Year Clinical Outcome Study

Linnemeier, Kennard, Soran, Kelsey,



University of Pittsburgh, Pittsburgh, PA
EECP therapy is shown to be an effective treatment option for diabetic angina patients. Although a majority of these patients were no longer considered candidates for further revascularization, in most cases, clinical benefit was sustained at one-year post therapy.

Two-Year Outcomes After Enhanced External Counterpulsation: Data From the International EECP Patient Registry

Michaels, Linnemeier, Soran, Kennard, UCSF, San Francisco, CA, University of Pittsburgh, Pittsburgh, PA

Two-year follow-up data showed a sustained benefit in 59% of patients who reported a reduction in angina symptoms upon completion of their initial course of EECP therapy.

Is Enhanced External Counterpulsation the Preferred Treatment for Chronic Stable Angina in Select Patients 75 Years and Older?

Linnemeier, Kennard, Kelsey, Soran, University of Pittsburgh, Pittsburgh, PA

Patients seek medical care to live longer or feel better. EECP therapy offers elderly patients, even those with extensive cardiovascular disease, a low-risk intervention that significantly reduces anginal symptoms, with cardiac event-free survival comparable to younger patients with similar symptoms.

Mayo Clinic

Enhanced External Counterpulsation Improves Endothelial Function in Patients with Coronary Artery Disease

Bonetti, Barsness, Keelan, Schnell, Pumper, Holmes, Higano, Lerman, Mayo Clinic, Rochester, MN

EECP enhances digital reactive hyperemic response as measured by Reactive Hyperemia Peripheral Arterial Tonometry.

In patients with a positive response to treatment, beneficial effects were seen to persist at one-month post-EECP therapy, suggesting improved endothelial function may contribute to the durable, positive therapeutic outcomes seen with EECP therapy.

Society for Cardiac Angiography and Intervention May 2003

Predictors of Failure to Achieve Angina Reduction in Patients Who Are Not Candidates for Invasive Revascularization Treated with Enhanced External Counterpulsation

Soran, Kennard, Kelsey, University of Pittsburgh, Pittsburgh, PA

While the majority of patients benefited, ARB use, history of congestive heart failure and previous EECP treatment were shown to be significant independent predictive factors of failure to achieve angina reduction in this patient population. Failure to achieve angina reduction strongly correlates with higher event and repeat EECP therapy rates at two-year follow-up. Careful patient selection may increase long-term success rates and significantly lower the need for repeat EECP treatments.

The American Heart Association Second Asia Pacific Scientific Forum June 2003

The Incidence and Independent Predictors of Repeat Enhanced External Counterpulsation in Patients with Left Ventricular Dysfunction

Soran, Kennard, Kelsey, University of Pittsburgh, Pittsburgh, PA

Patients with left ventricular dysfunction (mean EF 27%) who completed a course of EECP treatment (mean course 36 hours) for chronic angina had a good outcome at one-year follow-up and experienced a low (13%) rate of repeat EECP therapy. Patients with left ventricular dysfunction with an EF <35% and those with hypertension were significantly more likely to return for additional EECP therapy.

Recent Publication

Enhanced External Counterpulsation in the Management of Angina in the Elderly
American Journal of Geriatric Cardiology
2003;12(2):90-94.

Linnemeier G, Michaels AD,
Soran O, Kennard E.



Form Compliance

IEPR-1

Six months:	95%
One year:	94%
Two years:	90%
Three years:	91%

IEPR-2

Six months:	86%
One year:	82%
Two years:	88%
Three years:	97%

INTERNATIONAL

Six months:	86%
One Year:	82%
Two years:	88%
Three years:	97%

IEPR CONTEST WINNERS:

Everyone can be a winner!!

Diabetes Study Challenge!

June through December 2003

- GOAL:** Achieve the Diabetes Study enrollment goal of 500 patients before Phase 2 ends!
- CHALLENGE & REWARD:** Enroll 5 patients WIN a PRIZE!
- FLASH!** YOU MAY ALREADY BE A WINNER! Already enrolled 20 patients? A SUR-PRIZE will be arriving soon! Enroll 5 more – win again!
- FINE PRINT:** Each participating site must have 90% compliance at all IEPR pre, post and follow-up time points, for all patients enrolled in Phase 2, to be a winner in the Diabetes Study Challenge.

Diabetes Challenge Winners:

Lori Hunt, RN

The Heart Group

Karen Manzo, RN

Cardiovascular Research Institute, Inc.

Brenda Rantala, RN

Heart Centers of America, LLC

Louanne Tempich, LPN

EECP Center of Pittsburgh

Men's Health Study Contest!

June through December 2003

- GOAL:** To increase compliance and follow-up in the Men's Health Study before Phase 2 enrollment ends!
- HOW:** 1) All sites that have enrolled 5 patients to date, have 90% compliance with pre, post and (if achieved) 6-month follow-up, are already winners!
2) Moving forward! Prizes will be awarded for every 3 additional patients enrolled, with at least 90% pre, post and 6-month follow-up compliance.
- PRIZES:** SUR-PRIZES!!!
- FINE PRINT:** Each participating site must have 90% compliance at all IEPR pre, post and follow-up time points, for all patients enrolled, to be a winner in the Men's Health Study Contest.

Men's Health Study Contest Winners:

Gail Driskill, RN

Shady Grove Adventist Cardiac Rehab

Kim Juusola, MA

Hennepin County Medical Center

Congratulations to our first round of winners!



Clinical Tips.....



Sara Parker, RN, at The Heart and Family Health Institute, Port St. Lucie, FL checks her diabetic patients' blood sugar levels daily before starting EECF therapy. If the level is less than 80, the patient is routinely given peanut butter crackers and orange juice.

Ron Schutz, MD, Heart Centers of America, Portland, OR, prefers Nitropaste to the sublingual or spray nitroglycerin for improving augmentation. Dr. Schutz feels it's easier to control the dose when using the paste.

Obesse, female patients can be a challenge when attaining a stable ECG. An effective ECG lead placement (after thorough skin prep with alcohol and NuPrep, and the addition of SignaGel to a good stress test electrode) is: White lead directly on the bone of the right shoulder, Black lead directly on the bone of the left shoulder, Green lead on the upper sternum, above the breasts. The addition of a tight-fitting sports bra can also be effective for reducing tissue movement and decreasing ECG artifact.

IEPR-2 PARTICIPATING SITES:

Site Name	Investigator	Coordinator
Advanced Angina Center, MPC	M. Saleem Seyal, MD	Dana Wagner, RN
Angina Center of Evansville	Ralph Millsaps, MD	Joseph Winterman, RN
Associates in Cardiovascular Medicine	Andrew Klaus, MD	Brett Elliott, BS
Avera McKennan Hospital	Kevin Vaska, MD	Carol Scholten, RN
Bergen Cardiology Associates	David Landers, MD	Debra Roditski, RN
Borgess Health and Fitness Center	Alicia Williams, DO	Julie Johnson, MA
Cardiology Associates	Steven Wolinsky, MD	Kim Bryan, LPN
Cardiology Consultants, Ltd.	Atul Shah, MD	Donna Mann, RN
Cardiovascular Research Institute, Inc.	Bruce Fleishman, MD	Karen Manzo, RN
Central Arkansas Cardiology	Charles Caldwell, MD	Carrie Limberg, LPN
Central Baptist Hospital	Pam Gage, RN	Lynn Nelson, RN
Christ Hospital	Marc Silver, MD	Carol Pisano, RN
Cleveland Clinic	Stephen Ellis, MD	Rosemary Kidd, RN
Consultants in Cardiovascular Disease	John Szawaluk, MD	Sue Simon, RN
Creighton University Cardiac Center	Paul Biddle, MD	Megan McCarthy
ECP Heart Center	Gerald Weisfogel, MD	Jewel Shanahan, MA
ECP Heart Center	Blaine Purcell, MD	Ambar Faridi
EECF Center of Jackson Purchase	Francis D'Urso, MD	Regina Williams, RRT
EECF Center of Pittsburgh	Thomas Pinto, MD	Louanne Tempich, LPN
Elliot Hospital	Robert Lavery, MD	Diane Carrier, RN
Granite Medical Group	Alan Berrick, MD	Barbara Brangiforte, LPN
Griffin Hospital	Kenneth Schwartz, MD	Judy Grenon, RN
Heart Centers of America	Ronald Schutz, MD	Brenda Rantala, RN
HeartGen	James Nahlik, MD	Kim Herbert, RN
HeartGen	James Nahlik, MD	Melissa Scheer
Hennepin County Medical Center	Brad Bart, MD	Kim Juusola, RN
Indiana Heart Associates	Donald Ziperman, MD	Shawna Toombs, EMT
JFK Medical Center	Norman Erenrich, MD	Angelica Patten, RN
Knoxville Cardiovascular Group	Stuart Bresee, MD	Donna Griggs, RN
Long Island Cardiology Associates	Edward Davison, MD	Diane Bonagura, RN
Mayo Clinic	Gregory Barsness, MD	Linda Tesmer, RN
Medical Institute of NJ	Leonard Moss, MD	Ellen Pateman, RN
Medicor Cardiology	Kenneth Sternberg, MD	Luz Vanaggas, LPN
Mercy Hospital Medical Center	William Wickemeyer, MD	Donna Gideon
Meriter Hospital	John Moses, MD	Patty Scanlon, RN
Minneapolis Heart Institute Foundation	Timothy Henry, MD	Heidi Streed, RN
Missouri Heart Center	James Elliot, MD	Jeanette Quick, RN
Moffitt Heart & Vascular Group	Jeffrey Mandak, MD	Anita Todd, RN
North Suburban Cardiology Group	Edward Pinsel, MD	Debbie Edgar, RN
Northwest Ohio Cardiology Consultants	Todd Monroe, MD	Diane Philip, RN
Our Lady of Lourdes Medical Center	Jan Weber, MD	Cheryl Marks, RN
San Lucas Hospital	Edgardo Bermudez, MD	Jose Valentin, MD
Scripps Center for Integrative Medicine	Erminia Guarneri, MD	Donna Gilligan, RN
Shady Grove Adventist Hospital	Dennis Friedman, MD	Gail Driskill, RN
Southwest Heart	Brenda Peart, MD	Cheri Moore, MA
St. Luke's Hospital	Michael Chandra, MD	Deb O'Neil, RN
Stanley Williams, MD	Stanley Williams, MD	Melissa Lyons
Staten Island Heart	James Lafferty, MD	Laura Ferrara, RN
Stony Brook University Hospital	William Lawson, MD	Denise D'Ambrosia, FNP
Susquehanna Cardiology Associates	Donald Nardone, MD	Gwen Hill, RN
The Heart Group	Tyrone Daniels, MD	Lori Hunt, RN
The Heart Group	James Pantano, MD	Ruth Ann Gerchufsky, RN
University of Virginia	Abdullah Kfoury, MD	Ellen Longmoore, CNMT
UPMC Health System	Ozlem Soran, MD	Renee Litrun, RN
Wake Heart Associates	R. Lee Jobe, MD	Sharon Knight, RRT
Wichita EECF Heart Center	Roger Evans, MD	Linda Rae Hillier, RN
William Beaumont Hospital	Peter McCullough, MD	Dianna Grayson, RRT
York Hospital	Kevin McCullum, MD	Maureen Izer, RN



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Platinum level: 100% on all IEPR forms:

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Cardiovascular Research Institute, Inc.
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EECP Center of Jackson Purchase
Elliot Hospital
Lyford Cay Hospital, Nassau, Bahamas
Mayo Clinic
Mercy Hospital Medical Center
North Suburban Cardiology Group
Northwest Ohio Cardiology Consultants
Shands Hospital
Southwest Heart
Staten Island Heart
The Heart Group
William Beaumont Hospital

Gold level: 95%-99% on all IEPR forms:

Angina Center of Evansville
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Cotton O'Neill Heart Center
ECP Heart Center, Las Vegas
EECP Center of Pittsburgh
Hennepin County Medical Center
Independence Cardiology
Integrative Cardiology
Jackson Purchase Medical Center
Mason City Clinic
Medicor Cardiology
Missouri Heart Center
Ochsner Foundation Hospital
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Riverside Regional Medical Center
Shady Grove Adventist Cardiac Rehab
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Cardiovascular Specialists
Heart Centers of America
Knoxville Cardiology Group
Minneapolis Heart Institute Foundation

Scripps Center for Integrative Medicine
St. Luke's Regional Medical Center
The Heart Care Group, PC
York Hospital

Way to go! Keep up the great work!!