

IEPR Newsletter

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Nichole Dwyer IEPR Data Manager

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I began working with the International Enhanced External Counterpulsation (EECP) Patient Registry (IEPR) early in 1998, when the registry first started. I entered data on the first few patients enrolled. Since then, I have been a privileged participant in its growth. The IEPR is in its second phase. Phase 1 closed to new patient enrollment in July 2001 with 5000 patients, and continues with 3 year follow-up on these patients. Phase 2 is currently enrolling toward a goal of 2500 patients, and will also continue with 3 year follow-up. With over 6000 patients, the IEPR has achieved national and international recognition.

I would like to take this opportunity to describe my function within the IEPR. As Data Manager, I oversee all data collection, from both domestic and international clinical sites, manage all of the communication with those sites, and of course, the IEPR newsletter.

One of the highlights for me as the Data Manager is the rapport that I have established with the participating sites coordinators. Without the cooperation of the IEPR coordinators, the IEPR would not be as successful as it has become. Even with demanding paperwork and patient loads, the IEPR coordinators still manage to collect and submit data on registry participants. Due to the voluntary nature of the IEPR, it takes an extremely strong work ethic to keep up with the data submission on a research project, yet the IEPR coordinators make it appear easy. I applaud their efforts.

Another of my duties is the IEPR Newsletter. I have implemented, designed and produced 4 volumes, 17 issues, of the IEPR newsletter. It has become my pet project and has grown from 3 to 12 pages. The newsletter is an excellent forum to report to the IEPR sites the clinical outcomes, data presentations and publications, clinical tips and other IEPR-related information. One thing that I would like to see more of in the newsletter are

contributions and articles from IEPR sites. Contributions are always welcome! I encourage everyone to write an article for the newsletter, anything relating to EECP, whether it is a personal experience, or a patient-related story.

Another exciting experience for me is the opportunity to attend meetings in conjunction with the Scientific Sessions at American

Heart Association (AHA) and American College of Cardiology (ACC). The meetings are an educational experience, as I always learn something new and exciting that benefits me professionally. An integral part of my experience at these meetings is the interaction that I have with Vasomedical personnel. Vasomedical has always been generous with their time and assistance.

Another exciting event at these meetings is the IEPR/Clinical Issues joint venture. This forum provides updates on the data in the registry as well as the opportunity to meet the investigators and coordinators that I have been so fortunate to work with, even if only with a rapport built over the phone. I encourage everyone that can to attend these meetings not only for the camaraderie, but also for the professional development.

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Look in the newsletter for updates of meeting activities.

With the combined efforts of the IEPR staff and the participating IEPR sites, the Registry continues to establish its presence in the cardiology community, making data integrity extremely important. This can be attained through continued, complete, and timely data submission. Coordinators are the key to accomplishing this; they are the heart of the IEPR. It is through their consistent effort that the IEPR will continue to be an established and respected source of information on the safety, efficacy and outcomes of EECp therapy.

I would like to emphasize that I am here to assist the IEPR sites, both investigators and coordinators. Be assured that there are never any questions that are not important. Any assistance that I can provide benefits both the person posing the question and the IEPR.

Please do not hesitate to contact me with any questions; I always look forward to speaking with you!

Nichole lives in the Southside neighborhood of Pittsburgh and enjoys attending concerts, reading and shopping.

The Importance of Form Compliance

Maintaining a High Level of Form Compliance

These past few weeks many of you have been receiving telephone calls and letters regarding your level of compliance with form submission for the Registry. We hate nagging all the time, but it is really important that we get forms with complete data, and that we receive all forms in a timely fashion.

The purpose of the IEPR is to obtain information about the patients undergoing EECp, the safety and efficacy of the procedure and the long-term outcome for the patients. In order to widely disseminate the information received, we rely on peer-reviewed publication in medical journals, as well as presentations at major cardiovascular meetings, such as the American Heart Association Scientific Sessions and the American College of Cardiology annual meeting. **In order to avoid any implications of bias, it is essential that we report not only all cases that are treated, but also the short and long term outcome of every case. In that way, we avoid the implication that only the successful patients are entered into the registry, and only successful cases are reported.**

The goal that we have set for compliance for IEPR-2 is 90% of patients followed at every time point. In order to maintain this high level of compliance, we must constantly and consistently be in contact with you regarding form submission. Thus, we contact you with phone calls and letters regarding form compliance that does not meet our standard. This form of communication is to inform you of a potential problem. If you have a problem getting the forms in at any time, for any reason, please give us a call. We will try to work with you to solve problems if it is within our power.

We do hope that this helps you understand how important it is to submit data. As always, we are here for your questions and comments. Please do not hesitate to call us.

Lisa Kennard, PhD
IEPR Coordinator

Heart Failure Data Added to Phase 2

- Why?** To expand Registry data on patients with Heart Failure
- When?** Starting February 3, 2003, or when you have received IRB approval
- What?** IEPR-2 Pre-EECP, Post-EECP, Continuation, Follow-Up forms are changed. The Kansas City Cardiomyopathy Questionnaire (KCCQ) was introduced. The Duke Activity Status Index (DASI) remains unchanged.
- How?** Changes will be discussed in training conference calls conducted by Nichole Dwyer, IEPR Data Manager. Questions prior to or after training can be directed to Nichole at 412-624-3764 or email at dwyer@edc.pitt.edu

Presentations at the ACC, March 2003

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

Linnemeier, Kennard, Soran, Kelsey
March 30, 2003 9:00 AM - 11:00 AM

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

Lawson, Barsness, Kennard, Kelsey
March 31, 2003 4:00 PM - 5:30 PM

Atrial Fibrillation Does Not Degrade the Clinical Benefits from Enhanced External Counterpulsation (EECP) Therapy in Patients with Chronic Angina: Results from The International EECP Patient Registry

Ochoa, O'Neill, Almany
April 1, 2003 9:00 AM - 11:00 AM

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

Linnemeier, Soran, Kennard, Kelsey
April 1, 2003 9:00 AM - 11:00 AM

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

Linnemeier, Kennard, Kelsey, Soran
April 1, 2003 9:00 AM - 11:00 AM

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

Michaels, Kennard, Linnemeier, Soran
April 1, 2003 9:00 AM - 11:00 AM

Publications

Enhanced External Counterpulsation for Relief of Angina in Patients with Diabetes: Safety, Efficacy and One-Year Clinical Outcomes

Linnemeier, Rutter, Barsness, Kennard, Nesto
(in press, *American Heart Journal*)

Enhanced External Counterpulsation in Treatment of the Elderly

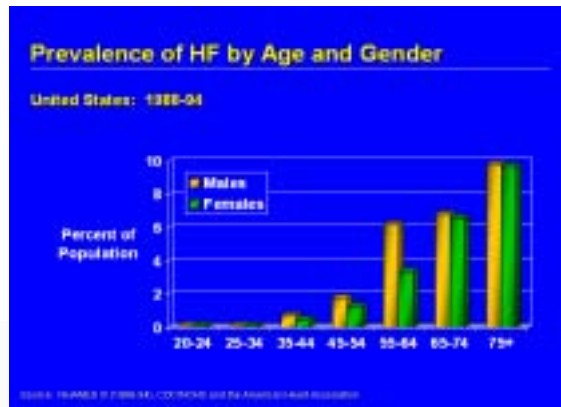
Linnemeier, Michaels, Soran, Kennard
(in press, *American Journal of Geriatric Cardiology*)

Heart Failure Data Enhances Phase 2

Upcoming Publications and Presentations

Treating Heart Failure Patients with EEC

The diagnostic and therapeutic landscape for heart failure (HF) has changed and continues to evolve. Centers providing EEC will be a part of this change.



A new classification system has been developed to emphasize both the evolution and progression of heart failure (Stages A-D). This new classification system is intended to complement, not replace, the New York Heart Association (NYHA) functional classifications, which primarily address symptoms in Stage C and Stage D patients. (see page 5 for NYHA classifications)



EECP is typically used to treat patients with angina refractory to medical therapy who are not good candidates for revascularization. These patients often have extensive coronary artery disease and previous infarctions which have resulted in poor left ventricular function and congestive heart failure (CHF). William Lawson et al. reported on the benefit and safety of EEC in this group of patients (*Cardiology* 2001; 96:78-84).

Of 1,957 patients enrolled in the IEPR with 6-month follow-up (available as of January 2001): 548 (28%) presented with a history of CHF.

In this group:

- 78% completed a course of treatment
- 68% reported angina improvement of one or more CCS functional class
- At 6 months, in the majority of patients, the improvement in angina was sustained
- There was a worsening of heart failure in 5.5% during the course of therapy

Before starting EEC, patients should be optimally medically managed for both HF and angina. An EEC therapist skilled in the assessment of cardiac patients and trained in the appropriate delivery of EEC therapy is key to the safe and effective administration of EEC treatment. Changes in symptoms, vital signs, weight, oxygen saturation, skin color, and / or mentation, or the presence of edema should be brought to the physician's attention before beginning the EEC treatment.

Thorough pre- and post-treatment patient assessment helps to promote the effectiveness of treatment and minimize adverse events. Vital signs, observations, and patient comments, should be carefully recorded on the "EECP Therapy Daily Record".

The potential for the occurrence of CHF during treatment in this high-risk group reinforces the need to perform a **physical assessment before and after** each treatment, **weigh** the patient **daily, examine** the patient **for peripheral edema prior to each** treatment session, and routinely measure **oxygen saturation** during EECP. EECP should be performed in an appropriate clinical setting by personnel trained to recognize and treat pulmonary edema. Ongoing assessment of the patient's clinical status is critical to safe and effective care. The relative rarity of cases of significant pulmonary congestion in this high-risk group suggests that EECP, with appropriate monitoring, may be safely administered to this group of patients.

Georgiann Linnemeier, MD
IEPR Medical Director

New York Heart Association Functional Classification:

Class I	Class II	Class III	Class IV
Patients with cardiac disease but <i>without</i> the resulting <i>limitations</i> of physical activity. Ordinary physical activity does not cause undue fatigue, palpitations, dyspnea, or anginal pain.	Patients with cardiac disease resulting in <i>slight limitation</i> of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitations, dyspnea, or angina pain.	Patients with cardiac disease resulting in <i>marked limitation</i> of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, dyspnea, or anginal pain.	Patients with cardiac disease resulting in <i>inability to carry on any physical activity without discomfort</i> . Symptoms of Heart Failure or the anginal syndrome may be present at rest. If any physical activity is undertaken, discomfort is increased.

*From the desk of
Georgiann
Linnemeier, MD,
IEPR Medical
Director*



Come Join Us!
at the
**3rd Annual
IETA General Membership Meeting!!**

at the
**American College of Cardiology Scientific Sessions
Chicago, Illinois
Saturday, March 29, 2003**

The program will include:
**IETA Business Meeting
Election Results
Billing and Reimbursement Panel Discussion
Q&A Open Forum**
Check: www.ietaonline.com for more information

See you in Chicago!

Please contact Jean French, Annual Meeting Committee Chair and 2nd Vice President at:
2ndvicepresident@ietaonline.com for more information.

IETA News

IEPR News

Clinical Tips

Clinical Tips

It is important to prevent dust and other contaminants from entering the inflation/deflation valves through the air inlets at the hose connections on the treatment table. Keeping the hoses connected at the end of the day is the easiest way to ensure that the patients' treatments are not compromised by poorly functioning valves.

If the proper size cuffs prove too long for a patient and the lower thigh cuff extends over the patient's knees:

- a. Apply the calf cuffs first, placing a piece of sheepskin behind the patient's knees and securing it with the upper edge of the calf cuff.
- b. Apply the lower thigh cuff, positioning the lower edge over the top edge of the calf cuff (and the sheepskin), behind the patient's knees. This will minimize the possibility of skin irritation, and any discomfort behind the knee from pressure of the lower thigh cuff.

DID YOU KNOW about a free American Heart Association program for Type 2 Diabetics?

In *Heart Quarters* from the 75th AHA Scientific Sessions 2002 newspaper; Tuesday, November 19, 2002 issue:

"A survey released by the American Heart Association says only 33% of people with type 2 diabetes consider heart disease to be among the 'most serious' diabetes related complications - even though 63% experience symptoms of cardiovascular disease. In fact, cardiovascular disease is the leading cause of death for people with diabetes, so these findings strongly suggest that most people with diabetes don't understand their risk.

"This disconnect prompted the American Heart Association to develop *The Heart of DiabetesSM: Understanding Insulin Resistance*, a free program that highlights the important connection between cardiovascular disease, diabetes and insulin resistance. It also provides tools to help people with type 2 diabetes reduce their risk.

"Participants receive a program guide, nutrition tips, and a weekly journal to track their blood pressure, cholesterol, glucose levels, weight and physical activity. They also receive a subscription to *Diabetes Positive*, a magazine that promotes positive living with diabetes.

"Throughout the program, participants receive continued communications from the American Heart Association about cholesterol management, physical activity, and nutrition.

"Anyone interested in participating in the *The Heart of Diabetes* can call 1-800-AHA-USA1 or visit the program's web site at americanheart.org/diabetes."

National and International IEPR Presence

A Comparison of Refractory Angina Patients Treated with Enhanced External Counterpulsation (EECP) from Turkey and the United States: A Report from the International EECP Patient Registry

Soran, Sengul, Ikizler, Yener, Kennard

Southern
Medical
Association

November
2002

EECP is a novel, non-invasive analogue of the intra-aortic balloon pump recently approved for use for the treatment of refractory angina. Although primarily used in the United States the treatment is now being used in other parts of the world. This study examines the safety and efficacy of EECP for the first cohort of Turkish patients and compares them with patients treated in the United States. (US)

Prior to 1998 the majority of the EECP studies took place at academic centers. The International EECP Patient Registry was designed to document the safety and efficacy of EECP in a variety of clinical settings. The unique aspect of this study is to enroll consecutive angina patients from academic and non-academic, hospital-based, free standing treatment centers with no exclusions due to demographics, clinical status or outcome. To date 4345 patients have been enrolled from US sites and 158 in other countries. Of these 39 were treated in Turkey (TR) .

TR were younger (57.8 vs. 67 years, $p < 0.001$) with a similar proportion of men (82% vs. 75%, $p = \text{NS}$). Duration of coronary artery disease was less at 9 years for TR and 11 years for US. Previous revascularization was less at 54% for TR vs 86% for US ($p < 0.001$). 55% of TR and 81% of US were no longer candidates for further revascularization. TR had less diabetes (25% vs. 42%, $p < 0.05$), hypertension (38% vs. 71%, $p < 0.001$), non-cardiac vascular disease (5% vs. 32%, $p < 0.001$). History of hyperlipidemia was similar in both groups (72% vs. 80%, $p = \text{NS}$). TR had less severe angina (Class III+IV+Unstable; 67% vs. 84% $p < 0.001$), similar multivessel disease (69% vs. 76%, $p = \text{NS}$) and less nitroglycerin usage (59% vs. 70%, $p < 0.01$). However, TR had higher history of congestive heart failure (56% vs. 32%, $p < 0.01$). More than half of the patients in both groups reported their health status and quality of life as very poor with unsatisfactory life styles. The rate of completion of the treatment course was higher in TR (92% vs. 83% $p = \text{NS}$). TR had higher diastolic augmentation ratios (1.21 vs. 0.79 $p < 0.001$).

After a mean treatment course of 35 hours, both groups showed a significant reduction in the severity of angina ($p < 0.001$), with 89% of TR and 74% of US reporting no angina or class I/II angina. Nitroglycerin use was discontinued in 43% of TR and 53% of US. Major adverse cardiovascular events during the treatment period (Death/CABG/PCI/MI) were low in both groups (2.4% vs. 2.7, $p = \text{NS}$). Post EECP evaluation of QoL, health status improvement and life style satisfaction showed significant increase in both groups ($p < 0.001$).

In conclusion Turkish patients presenting for EECP treatment show very different baseline profiles with respect to risk factors, medical history, comorbidities and anginal symptoms. However both cohorts achieved substantial reduction in angina and improvement in QoL with EECP despite an unfavorable baseline profile.

Heart Healthy Recipes



Morning Glory Muffins

- 2 cups flour
- 3/4 cup sugar
- 2 teaspoons baking soda
- 2 teaspoons cinnamon
- 1/4 teaspoon salt
- egg substitute (equivalent to 4 eggs)
- 1/2 cup vegetable oil
- 1/2 cup unsweetened applesauce
- 2 teaspoons vanilla
- 2 cups peeled & chopped apples
- 1/2 cup raisins
- 2 tablespoons chopped pecans
- 3/4 cup grated carrots

Preheat oven to 350 degrees. Spray muffin tin with nonstick spray or use paper muffin liners. In a large bowl, mix together the flour, sugar, soda, cinnamon and salt. In another bowl, combine the egg substitute, oil, applesauce and vanilla. Stir in the apples, raisins and carrots. Add to the flour mixture and stir until just blended. Spoon batter into muffin tins, filling 2/3 full. Sprinkle with chopped pecans and bake for 35 minutes or until springy to the touch. Let cool for 5 minutes, then remove from pan to a rack and let cool completely. Note: these freeze well. They may be rewarmed before serving. Yield: 18 small muffins.

Nutritional Analysis	
Calories	180
Fat (gms)	7
% calories from fat	35
% polyunsaturated	20
% saturated	5
% monounsaturated	10
Cholesterol (mgs)	trace
Sodium (mgs)	150
Protein (gms)	3
Carbohydrate (gms)	26
Fiber (gms)	1.5

Note: People with diabetes or those on calorie-controlled diets may count 1 muffin as 1 starch, 1 fruit, 3 fat servings.

**Chinese Noodles with Spring
Vegetables**

- 1 package (8 ounces) chinese noodles
- 1 tablespoon peanut oil
- 1 tablespoon sesame oil
- 1 tablespoon grated fresh ginger
- 2 cloves garlic, finely chopped
- 2 tablespoons reduced-sodium soy sauce
- 1 cup broccoli florets
- 1 cup fresh bean sprouts
- 8 cherry tomatoes, halved
- 1 cup chopped spinach
- 2 scallions, chopped
- Crushed red chili flakes (optional)

Cook noodles until al dente, do not over cook. Drain in a colander and rinse with cold water. Set aside.

Heat oils in a large stockpot or frying pan. Add ginger and garlic and stir-fry until fragrant. Add soy sauce and broccoli and continue to cook over medium heat for about 3 minutes. Add remaining vegetables and toss. Toss until warmed through and serve immediately. Season with crushed red chili flakes, if desired.

Yield: 4 servings

Nutritional Analysis	
Calories	270
Dietary fiber (gms)	5
Fat (grams)	9
% of calories from fat	30
% polyunsaturated	10
% saturated	7
% monounsaturated	13
Cholesterol (mgs)	0
Sodium (mgs)	350
Protein (gms)	9
Carbohydrate (gms)	38

Note: People with diabetes or those on calorie-controlled diets may count one serving as 2 starch, 2 vegetables, 2 fat.