



Identifying the Patient for EECp® Therapy

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At the present time, under Medicare Coverage Policy (35-74), reimbursement is provided for the use of EECp® therapy for patients diagnosed with disabling angina (Canadian Cardiovascular Society Angina Class III or IV, or equivalent classification) who, in the opinion of a cardiologist or cardio-thoracic surgeon, are not readily amenable to surgical intervention such as PTCA or cardiac bypass because: (1) their condition is inoperable, or at high risk of operative complications or post-operative failure; (2) their coronary anatomy is not readily amenable to such procedures; or (3) they have co-morbid conditions which create excessive risk. Most private insurance carriers offer reimbursement for EECp therapy and have established coverage criteria similar to Medicare. Angina pectoris is defined as chest pain or discomfort (that may be manifested as sub-sternal pressure, a feeling of strangulation or suffocation, heaviness in the chest, fatigue, "indigestion", shortness of breath, or pain in the left arm or the jaw) that has objective evidence of being cardiac in origin.

Often, when patients are asked if they have "chest pain" they will answer, "NO." If you ask how many episodes of "chest pain" they've had since their last visit they may reply, "NONE." They are not withholding information or becoming uncooperative; the problem may be that we are not asking them the correct questions or asking the questions correctly. As their cardiac illness progresses some patients may alter their behavior, consciously or unconsciously avoiding activities that provoke anginal symptoms, sometimes to the point of becoming completely sedentary. For others it is a matter of degree – the sudden realization that their symptoms no longer permit them to sustain the level of activity they were accustomed to in the past.

IEPR

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One of my patients came to the office concerned that he could no longer play his usual five games of tennis; he could only play three. After a thorough cardiac work up he was found to have severe triple vessel coronary artery disease with a left ventricular ejection fraction of 35%, and 1 mm size vessels. The surgeons felt he was not a good surgical candidate so he had EECp and soon was again enjoying his usual five games of tennis. Before EECp this patient always denied having "chest pain" but with more questioning acknowledged experiencing chest tightness, with a feeling of suffocation and fatigue, after the first game of tennis. Our nurse practitioner had a similar experience with a patient who denied having any angina pectoris. His wife told us that the patient was so lazy that he would not even comb his own hair or put on his own socks. Further questioning revealed that each time the patient did these things he would feel fatigued and become short of breath. It was not what we asked but the words we chose to ask it.

Learning from such experiences we designed a patient questionnaire that in layman's terms asks questions regarding the patient's symptoms. This simple questionnaire has proven very effective, helping us identify CAD patients that might otherwise have gone undetected. Training our staff to recognize symptoms has made them active participants in the patients' improvement and success. Alert and knowledgeable, the staff has become an invaluable adjunct for identifying patients for EECp therapy.

Most patients respond positively to EECP treatment. Not all get complete angina relief, but the quality of their lives is typically significantly improved. The patient that could not comb his hair or put on his own socks is now able to do these things, and more, for himself. However, he still gets his angina when he starts running after his granddaughter. His wife no longer describes him as a lazy person, and he has been able to stop taking his anti-depressant medications. There are those who will argue that the EECP treatment did not work because the patient still has some angina. The patient had no surgical options, was no longer responding to medical therapy and was depressed by his inability to participate in even the most basic aspects of his own care. EECP therapy provided a viable and effective solution, significantly improving the patient's quality of life, despite some residual (but manageable) angina.

Because EECP is currently reimbursed for the chronic and stable patient with angina pectoris, the emergency room is not a likely source of referrals for EECP therapy; those patients are acute. The cardiac catheterization laboratory, the cardiac catheterization review conference, cardiology clinic, physician colleagues, nurse practitioners, physicians' assistants, and your own patients could all be potential referral resources. Educating physician colleagues and their staff will likely prove to be time well spent. Our practice does in-services in the offices of the physicians who refer patients to us for EECP. We bring lunch and give a ten-minute lecture on EECP from the patient's point of view. We even invite some of that practice's successfully treated patients so they can tell their own stories about the benefits of EECP therapy.

It is important to keep in mind that not all patients are EECP candidates. A patient's motivation to become an active participant in his/her health care is an important ingredient in the success of any treatment. A motivated patient who will accept the responsibility of coming for 35 to 45 treatment sessions, and who is willing to initiate and sustain the lifestyle changes so important to maintaining the benefits of the seven weeks of EECP therapy, contributes a great deal to his/her own successful outcome. Personally screening the patients referred to us and inviting the referring physicians to become a participant in the screening process does much to assure that the patients selected for EECP therapy will have the best possible outcomes. Here is an opportunity to educate without insulting, and to make a colleague a hero in his/her patients' eyes when the patients return to that practice improved and happy.

Careful selection is key to identifying a patient for EECP therapy – careful selection through careful screening of the patients, and careful selection of the words chosen to ask the questions that will identify the best candidates for EECP therapy.

Recent Publications:

Lawson WE, Hui JCK, Barsness GW, Kennard ED, Kelsey SF. Effectiveness of Enhanced External Counterpulsation in Patients with Left Main Disease (for the IEPR investigators). *Clin. Cardiol.* 2004 27, 459-463.

Recent Presentations:

European Society of Cardiology, Munich, Germany • August 29–September 1, 2004

Comparison of Clinical Outcomes, Rates of Event Free Survival, and Repeat Enhanced External Counterpulsation (EECP) in Women and Men Undergoing EECP for Angina Management

ZO Soran

Diabetic Patients Have a Good Response to Enhanced External Counterpulsation (EECP) Despite Lower Diastolic Augmentation than Non-Diabetics

AS Brown

Heart Failure Society of America, Toronto, Canada • September 12–15, 2004

Comparison of Abbreviated Versus Full Course of Enhanced External Counterpulsation in Heart Failure Patients with One-Year Follow-up

WE Lawson

The Impact of Diastolic Augmentation Ratio on Treatment Outcomes in Patients with Left Ventricular Dysfunction Treated with Enhanced External Counterpulsation for Angina Management

ZO Soran

Trans Catheter Therapeutics, Washington, DC • September 27–30, 2004

Does Prior Angioplasty Affect the Benefit of Enhanced External Counterpulsation in Diabetics?

WE Lawson

Mediterranean Association of Cardiology and Cardiothoracic Surgery, Bodrum, Turkey September 26–29, 2004

Comparison of Clinical Outcomes, Event Free Survival and Repeat Enhanced External Counterpulsation (EECP) Rates for Turkish and US Coronary Artery Disease Patients Treated with EECP for Angina Management

ZO Soran

IEPR Phase-1 Completes Three-year Follow-up Phase-2 Achieves Enrollment Goal

Lisa Kennard, PhD, IEPR Coordinator

Congratulations to all the IEPR-1 Investigators and Coordinators on the completion of the three-year follow-up of the first phase of the International EECF Patient Registry. We wish to express our gratitude and appreciation to the thirty-eight participating clinical sites for their continued support, and the high level of compliance they so consistently maintained over the years. Thanks to their diligence and hard work the Registry has been remarkably successful at introducing EECF to the wider cardiology and medical communities. The data these EECF centers provided were the basis for the 14 manuscripts published in peer-reviewed journals, and the 69 presentations at national and international cardiology meetings to date. Quite an accomplishment!

Analyses on the complete Phase-1 data will continue. There are still many thought-provoking and enlightening topics waiting to be published. The Registry is always interested in ideas for additional publications. Investigators and Coordinators are invited to contact me (412-624-5217, Kennard@edc.gsph.pitt.edu) if you would like to pursue an analysis topic for a manuscript submission to a medical, nursing or other professional journal.

Still ongoing, IEPR Phase-2 is well on its way to even greater success with an expanded data set that includes heart failure. The enrollment goal of 2500 patients was achieved in September 2004, and two-year follow-up is well underway with remarkable, greater than 95% compliance at all time points. Kudos to the Phase-2 participants! We look forward to many interesting publications emerging from the Phase-2 data.

For complete bibliographies visit:

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

the Vasomedical website: www.eecp.com

★ SUB-STUDY STARS ★

Men's Health Study

Shady Grove Adventist Hospital
Cardiac Rehab and EECF Center
Dennis Friedman, MD
Gail Driskill, RN

Hennepin County Medical Center
Bradley A. Bart, MD
Kim LaNasa, MA, EPC

Diabetes Study

Cardiovascular Research Institute, Inc.
Bruce Fleishman, MD
Karen Manzo, RN

Heart Centers of America, LLC
Ronald Schutz, MD
Brenda Rantala, RN

EECF Center of Pittsburgh
Thomas Pinto, MD
Louanne Tempich, LPN, RCVT

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Maureen Izer, RN
York Hospital
York, PA

Laura Ferrara, RN
Staten Island Heart
Staten Island, NY

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

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-EECF: 98%
Post-EECF: 100%
Six Months: 95%
One Year: 97%
Two Years: 97%

IEPR Site Spotlight:

Heart Centers of America, Portland, OR

Ronald W. Schutz, MD, Medical Director • Brenda Rantala, RN, Clinical Director • Maureen Genera, LPN, EECF Therapist

Heat Centers of America opened in April of 1999 and is located adjacent to Legacy Good Samaritan Hospital in Portland, Oregon. It was the first facility to offer EECF treatment in the Portland area and the Pacific Northwest. Ronald W. Schutz, M.D. is the Medical Director of Heart Centers of America. Dr. Schutz is board certified in internal medicine and cardiology, and has practiced in the field of cardiology since 1980. Brenda Rantala, RN, our Clinical Director, has experience in Cardiac Rehabilitation, Cardiac Surgery Case Management, Cardiac Research, and ICU/CCU. Brenda took over the position of Clinical Director in 2001 from Brenda Hammock, RN, who opened the clinic with Dr. Schutz in 1999. Maureen Genera, LPN joined our staff in 2001 after being employed at Whitaker Wellness Institute in Newport Beach, CA.

Back in 1999, because EECF was not a well-known treatment modality for angina patients, cardiologists were reluctant to refer patients to our clinic. In fact, initially Dr. Schutz took some pretty serious ribbing from his cardiologist colleagues, and was jokingly referred to by some as the "voodoo doctor." Slowly, as physicians referred patients to treatment, and those patients experienced dramatic improvements in their angina symptoms, the skeptics became believers.

We currently have three MC-2 treatment systems and have the capacity to treat 16 patients per day. Our average census is ten patients per day. We have participated in the IEPR since our opening in 1999 and enrolled 72 patients in IEPR-1 and 112 patients in IEPR-2. Our outcomes parallel published results. To date, our facility has treated over 210 patients.

Our interest in EECF research is not limited to data collection for the IEPR. In 2001, in response to inquiries from local athletes who had heard that EECF might improve athletic performance, Heart Centers of America joined efforts with Nike, Inc. to test the hypothesis that EECF could improve athletic performance. Nineteen vigorously active males were randomly assigned to treatment (n=10) and

placebo (n=9) groups. Both groups completed 35 one-hour sessions. The treatment group received standard treatment pressure while the placebo group received 80 mmHg pressure. Physiological parameters were measured at baseline and within one week following the completion of treatment. These tests included: aerobic capacity (VO₂ max), maximum tolerance for lactic acid, work tolerance time (WTT) to exhaustion for standard exercise, and lactate threshold for progressive increments in exercise intensity. Other measures of physiological interest were maximum ventilation for exhausting exercise, maximum heart rate during exhausting exercise and postural instability and ataxia. After analyzing the data, the only significant difference between the groups was a small increase in the WTT in the placebo group and a statistically significant improvement in postural stability in the treatment group. We concluded that EECF treatments had no significant effect on the physiological parameters considered to be among the best for predicting performance in endurance-type competitive sports.



(from l to r) Brenda Rantala, RN, Ronald Schutz, MD, Maureen Genera, LPN

Because of the positive effect noted with postural stability in the athletes undergoing EECF in the Nike study, and our clinical observations with our own angina patients, we are currently enrolling angina patients in a study titled "Improvement of Postural Stability and Ataxia During Enhanced External Counterpulsation (EECP)." With equipment on loan to us from NASA, we are measuring balance and postural stability using computerized dynamic posturography. Our patients are tested at baseline, weekly during their treatment course, and at treatment end. We have enrolled 12 patients to date with a target enrollment of 20.

Although our staff enjoys participating in data collection for the IEPR and our own research projects, providing care for our EECF patients is our main focus and source of satisfaction. Our goal is not only to provide EECF therapy, but also to offer a comfortable, supportive atmosphere for our patients. Because EECF is not a cure, we also focus on patient education and risk factor modification. We are

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focus on patient education and risk factor modification. We are continually amazed how many of our patients are not aware of their own risk factors and the measures they can take to decrease the risk of worsening their coronary artery disease. Based on their individual risk factors, our patients are given information and instruction on smoking cessation, low cholesterol, low saturated fat, and sodium reduction diets, stress reduction techniques, and exercising.

In 2001, after we added our third treatment system, it became very apparent that we needed to have a more focused approach to exercise instruction. One morning, as our Clinical Director was working in her office, she overheard a conversation between three of the EECF patients. One patient was asking the other two "How many did you do this morning?" The other two patients were quickly and proudly responding with, "I did three" from one and, "I did five" from the other. Thinking they were talking about nitroglycerine (NTG) tablets, the Clinical Director went on with her work. The next day, she heard a similar exchange between the same patients. Concerned that these patients were requiring so much NTG so late in their treatment courses she went to the treatment room to speak with them. When she started asking them more questions about their NTG use they laughed and told her, "We aren't talking about NTG use; we are talking about how many flights of stairs we climbed to the clinic this morning!" Those particular patients had been testing their exercise tolerance by climbing flights of stairs to the clinic and, not only that; they were encouraging and challenging other patients to do the same. Although this may have been a good motivator for some of the patients, both Dr. Schutz and Brenda had frightening images of having to explain an "exercising" EECF patient code in the Physicians Office Building stairwell to the Code 99 committee.

We now work collaboratively with almost all of the Cardiac Rehabilitation programs in the metropolitan area. During the third or fourth week of EECF therapy, when patients typically experience an increase in exercise tolerance, they begin monitored Phase II exercise in a Cardiac Rehabilitation program. We have found that this is also helpful in evaluating treatment effectiveness and changes in exercise tolerance. In addition, since most of the rehabilitation programs are 13 weeks in length, it provides a support system for our patients once they have finished their EECF treatment course.

We have seen many changes over the past five years. The long list of exclusions has become precautions, and we have successfully treated many patients who previously were considered to have contraindications to EECF therapy. We treated several patients who had non-surgical abdominal aortic aneurysms without complications. These patients are routinely monitored with abdominal ultrasound examinations at three and seven weeks. We safely and successfully treat patients on Coumadin therapy with INR's as high as 3.0. INR levels are monitored every two weeks and we

watch closely for lower extremity bruising. Patients who have pacemakers can have therapy, usually after the rate response feature is turned off.

Our experience has provided us with a few "pearls of wisdom":

- We monitor pre and post CBG's on all insulin dependent diabetics to detect post treatment hypoglycemia.
- We use Nitro-Paste during the treatment hour to enhance augmentation for patients whose augmentation is less than 0.7.
- For patients with severe back pain or recent back surgery, we can administer treatment with the patient in the prone position.
- We administer pre-treatment Gaviscon for patients with GERD who experience symptoms during treatment.
- For patients with GERD we pad the abdomen with cut pieces of egg crate for comfort.
- Our insulin-dependent diabetic patients wear pantyhose under their treatment tights to prevent skin irritation.
- We utilize the seven-week treatment course to up-titrate medications, such as Coreg, that benefit from close observation.
- For patients with pre-tibial tenderness we use garden pads that have been cut length-wise and applied in an upside down "V" formation over the shins.
- For patients with lower back injuries and strain we elevate the knees with pillows.
- We have had custom vinyl fitted sheets made for the treatment beds that allow padding for comfort, and easy cleaning between patients (information can be obtained at www.angelfire.com/linux/medbedcovers).

We have enjoyed many success stories over the past five years. Perhaps our most dramatic was the patient who had been experiencing increasing levels of debilitating angina and finally had an MI. In the hospital he was told to "get his affairs in order" and was referred to EECF as a last resort. He came to the clinic extremely depressed and without much hope. Over the previous two years he had been forced to give up acting in the local community theater, and he was no longer able to travel to see his grandchildren. At the start of his EECF treatments his wife had to use a wheelchair to get him from the car to the clinic. Halfway through his treatment course he was able to walk from the car to the clinic, and he was walking ten minutes twice a day. By the end of his treatment course he was walking

30 minutes per day. Two months after his treatment course he took his family, including his grandchildren, on a three-week trip to Ireland. Shortly after that he starred in a local theater production. Several of us from the clinic were invited to attend the play. Sitting in the audience we all realized, once again, how lucky we were to be able to have such a dramatic and positive impact on patients' lives - that is what keeps us coming to work every day!





IEPR

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Compliance Champions!

PLATINUM - 99-100%

Avera McKennan Hospital
The Angina Center at Ohio Valley Heart
Cardiovascular Associates of N. Wisconsin
Cardiovascular Research Institute, Inc.
Central Arkansas Cardiology
Christ Hospital and Medical Center
Consultants in Cardiovascular Disease, Inc.
Creighton University Cardiac Center
Edgardo Bermudez, MD
Elliott Hospital
Griffin Hospital
The Heart Care Group

The Heart Group
Independence Cardiology Associates
Integrative Cardiology
Jackson Purchase Medical Center
Knoxville Cardiovascular Group
Mason City Clinic, Mercy Heart Center
Mayo Clinic, Saint Mary's Hospital
Mercy Hospital Medical Center
Missouri Heart Center
Moffitt Heart and Vascular Group
Monmouth Cardiology Associates
North Suburban Cardiology Group

Northwest Ohio Cardiology Consultants
Oregon Cardiology
Ochsner Foundation Hospital
Our Lady of Lourdes Medical Center
Riverside Regional Medical Center
Scripps Center for Integrative Medicine
Shady Grove Adventist Cardiac Rehab
Shands Hospital
SUNY Stony Brook
University of Pittsburgh Medical Center
University of Virginia
Wisconsin Heart

GOLD - 95-98%

Cardiovascular Specialists
Central Baptist Hospital
Cotton O'Neil Heart Center
EECP Center of Northwest Ohio

EECP Center of Pittsburgh
EECP of Nassau
Hammersmith Hospital

Heart Centers of America, LLC
Medicor Cardiology
St. Luke's Regional Medical Center

SILVER - 90-94%

Advanced Heart Care
Associates in Cardiovascular Medicine
Granite Medical Group

Hennepin County Medical Center
Minneapolis Heart Institute Foundation
Southwest Heart

Staten Island Heart
Susquehanna Cardiology Associates
Vital Heart