

# EECP<sup>®</sup> Newsletter

Updating our clinical knowledge on an evidence-based therapy

VOLUME 2, ISSUE 1



## REPEAT TREATMENT WITH EECP<sup>®</sup> THERAPY

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**FDA 510(k) Clearance:** The Food and Drug Administration (FDA) has cleared EECP external counterpulsation devices for use in unstable and stable angina pectoris, acute myocardial infarction, congestive heart failure and cardiogenic shock. Currently in the United States, EECP therapy is used mainly for the treatment of patients who suffer from coronary artery disease refractory to medical and/or surgical therapy.

**Coverage:** EECP therapy is covered by the Center for Medicare and Medicaid Services (CMS) and many insurance companies for patients who have been diagnosed with disabling angina (Class III or Class IV, Canadian Cardiovascular Society Classification or equivalent classification) who in the opinion of a cardiologist or cardiothoracic surgeon are refractory to optimal medical therapy and not readily amenable to surgical intervention such as percutaneous transluminal coronary angioplasty (PTCA) or cardiac bypass because their condition is inoperable, and/or their coronary anatomy is not readily amenable to such procedures, and/or they have co-morbid conditions which can create excessive risk. The current course of EECP treatment usually consists of one-hour sessions, five days a week, for seven weeks for a total of 35 hours. CMS makes no policy statement on the coverage of repeat EECP treatment, similar to other major revascularization therapies such as percutaneous coronary intervention (PCI) or coronary bypass surgery.

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## VASOMEDICAL RECEIVES FDA 510(K) CLEARANCE TO MARKET HOLTER MONITORING PRODUCTS

The Vasomedical-BIOX 1305 Holter Monitor is the latest addition to Vasomedical's product line. It has already received CE Marking certification to market in the EU countries, is a compact, lightweight, 3-channel ECG Holter monitor designed for monitoring a patient's cardiac rhythm for 24 to 72 hours and recording ECG on a standard SD memory card. It features a high signal sampling rate and high resolution digital recording for comprehensive data analysis. The data recorded on the 1305 monitor is utilized in the early detection of cardiac abnormalities such as ischemia and arrhythmia. Data recorded by the Model 1305 can be quickly analyzed using the proprietary Vasomedical-BIOX CB Series Analysis Software. *Learn more at [www.vasomedical.com](http://www.vasomedical.com).*



### HIGHLIGHTS

#### Current Issue

→ LEARN HOW YOUR PATIENTS CAN BENEFIT FROM A REPEAT COURSE OF EECP TREATMENT

→ VASOMEDICAL RECEIVES FDA 510(K) CLEARANCE FOR HOLTER MONITORING PRODUCTS

#### Next Issue

→ TREATING AND BILLING FOR HEART FAILURE PATIENTS

### NEWS & EVENTS

→ NEW FORUM FOR PATIENTS AND MEDICAL PROFESSIONALS LAUNCHED

[WWW.EECPFORUM.COM](http://WWW.EECPFORUM.COM)

→ EECP PRESENTED AT AHA 2009 QCOR CONFERENCE

→ RESULTS OF TWO RANDOMIZED, CONTROLLED CLINICAL STUDIES PRESENTED AT ACC 2009


**Current Market:** Angina affects 6.8 million people in the United States with 400,000 new cases of stable angina diagnosed annually. It is estimated that approximately 80,000-100,000 patients suffer with refractory angina symptoms inadequately relieved by medical therapy. There are approximately 650 EECP therapy providers treating an estimated 18,000 patients annually in the United States, and approximately 120 providers in 29 countries internationally treating approximately 4,000 patients.

**Long-Term Benefits:** A three-year follow-up study of 1,427 patients from 36 centers registered in the International EECP Patient Registry (IEPR) - Phase I (IEPR-1) was reported by Dr. Poay H. Loh and colleagues in the April 2008 issue of *Clinical Cardiology*. Immediately post-EECP, the proportion of patients with severe angina (Canadian Cardiovascular Angina Classification [CCS] III/IV) was reduced from 89% to 25%,  $p < 0.001$ . The CCS class was improved by at least one class in 78% of the patients and by at least two classes in 38% of patients. This was sustained in 74% of patients at 3-year follow-up. Approximately 75% of refractory angina patients who received EECP therapy completed the full course (30-35 hours) of treatment; there is a subgroup of these patients who also benefited from a repeat course of therapy to maintain the benefits achieved after the initial course. For the 10-25% of patients who do not achieve these long-term benefits, a routine repeat course of EECP therapy may prove beneficial.

**Clinical Benefits of Repeat EECP treatment:** Patients who undergo repeat EECP treatment can be subgrouped into three different categories:

- those who experience clinical benefits after a full course of EECP treatment and want to maintain the achieved benefits,
- those who completed a full course with residual angina, and
- those who failed to complete a full initial course of at least 30 hours of EECP treatment.

The most common reasons for re-treatment are recurrent angina, persistent angina, and failure to complete the initial course of therapy.



*69.4% of patients improve by at least one class with repeat EECP treatment.*

Available data on the indications, frequency, and efficacy of re-treatment are derived mainly from the IEPR—Phases 1 and 2. To examine the causes and results of retreatment of patients who failed to complete an initial 35-hour EECP course, data of 2,311 successive angina patients from the IEPR-1 were analyzed by Dr. William Lawson and colleagues. 86.5% of the patients completed the EECP course (Complete) and 3.5% of patients did not complete the initial course of EECP treatment (Incomplete), mainly because of the patient's preference and adverse events. 28.3% of the Incomplete cohort had repeat EECP therapy within 1 year vs. 10.1% of the Complete group. In addition, approximately 18% of patients who completed the initial course of EECP therapy underwent re-treatment at 2-years post treatment.

For the Complete group, 83.4% had a reduction of at least one CCS class after their initial EECP course, vs. 21.7% in the Incomplete group ( $p < 0.001$ ). After repeat treatment, 66.2% of the Incomplete group achieved at least one CCS class reduction vs. 69.4% of the Complete group ( $p = NS$ ) undergoing retreatment. The independent predictors for those who return to successfully complete their second course were patients who stopped their first course because of clinical events, and candidacy for coronary artery bypass grafting at the time of initial treatment. The results of retreatment of those who failed to complete their initial EECP course were comparable to those who completed their initial treatment, with similar reductions of CCS angina class. However, the reasons for not completing the first course of therapy must be considered carefully and adequately addressed before re-treatment is started.

**Reimbursement for Repeat Treatment:** Reimbursement coverage issues largely determine whether re-treatment is covered and provided to patients. Patients failing to complete the initial course of treatment are generally eligible for reimbursement to cover an additional 35 hour course at a later date. Re-treatment is generally covered when the physician provides reasons for re-treatment including documenting the patient's angina or anginal equivalent severity, comorbidities, response to the initial course of therapy, and antianginal treatment regimen.

Insurance carriers typically approve extensions of the initial course of treatment, generally 10–15 hours. In some cases an additional 35 hours of treatment has been approved. These extensions of therapy might be contingent on a favorable, but incomplete, response to the initial therapy, indicated by alleviation of angina, decrease in antianginal medication use, or improvements on radio-nuclide stress test perfusion imaging or exercise tolerance. According to IEPR data, re-treatment typically occurred after a median interval of 378 days from the end of the initial therapy.

The key to successful reimbursement for repeat EECF treatment include physician support, clear and specific documentation of the patient's angina severity and demonstrable benefits from previous EECF treatment. EECF therapists or billing clerks may need to contact patients' insurers to pre-qualify their eligibility, coverage, deductible and co-pay as well as determination of facility contract agreement with carriers. CMS guidelines may differ from state to state or between regions.

Some Medicare carriers accept the National Coverage Determination (NCD) without further qualification and place no limit to the hours of EECF treatment nor the frequency of treatment, as long as the patient meets the guideline criteria for CMS coverage. Some carriers limit the total number of treatment hours per one or two years, and how soon after completing a full course of treatment a patient may receive repeat treatment. For example, Florida Medicare allows EECF treatment once in a 12-month period. When the initial request for coverage of repeat treatment has been denied, an appeal with simple, clear and adequate physician documentation supporting the need and benefits of EECF re-treatment usually ends with successful payment, especially when repeat EECF treatment meets the state's Medicare or patients' carriers rules and criteria.

EECF therapy continues to provide health benefits and an improved quality of life to patients suffering from refractory angina who are not candidates for surgery or revascularization. These patients continue to enjoy their families, activities and make the most of their lives after completing their initial round of therapy. A sustained benefit was demonstrated in most patients (75-85%) who participated in the IEPR 3-5 years post-treatment. For those patients who fail to complete their first round of therapy, still have symptoms,, or have a return of symptoms, repeat EECF sessions have shown successful patient outcomes with healthcare coverage.



*Re-treatment is generally covered when the physician documents the patient's angina severity, comorbidities, response to the initial course of therapy, and antianginal treatment alternatives.*

1. American Heart Association, Heart Disease and Stroke Facts – 2005 Update. Available at: <http://www.americanheart.org/downloadable/heart/1105390918119HDSStats2005Update.pdf>, p. 53.
2. 2002 National Hospital Discharge Survey, March 2005. Available at: [http://www.cdc.gov/nchs/data/series/sr\\_13/sr13\\_158.pdf](http://www.cdc.gov/nchs/data/series/sr_13/sr13_158.pdf), Table 45, p. 61

3. Loh PH, Cleland JG, Louis AA, *et al.* Enhanced External Counterpulsation in the Treatment of Chronic Refractory Angina: A Long-term Follow-up Outcome from the International Enhanced External Counterpulsation Patient Registry. *Clinical Cardiology*. 2008 Apr 10;31(4):159-164.
4. Lawson WE, Barsness G, Michaels AD, *et al.* Effectiveness of Repeat Enhanced External Counterpulsation for Refractory Angina in Patients Failing to Complete an Initial Course of Therapy. *Cardiology*. 2006 Nov 1;108(3):170-175 [Epub ahead of print].
5. Michaels AD, Barsness GW, Soran O, *et al* for the International EECPP Patient Registry Investigators. Frequency and Efficacy of Repeat Enhanced External Counterpulsation for Stable Angina Pectoris. (from the International EECPP Patient Registry). *American Journal of Cardiology*. 2005 Feb;95(3):394-397.
6. Michaels AD, McCullough PA, Soran OZ, *et al.* Primer: Practical Approach to the Selection of Patients for and Application of EECPP. *Nature Clinical Practice Cardiovascular Medicine*. 2006 Nov;3(11):623-632.

If you have a story idea or would like to share the results of your experience with other clinicians, please e-mail your idea/story to: Kasia Smigielska, Marketing Manager at [ksmig@vasomedical.com](mailto:ksmig@vasomedical.com).

## RECENT PUBLICATIONS & PRESENTATIONS

### **EECP: A Non-invasive Therapy for Refractory Angina**

Beaini Y, Morley C.

*Practitioner*. 2009 Feb;253(1715):27-31.

### **Invasive Left Ventricular Energetics During Enhanced External Counterpulsation**

Michaels AD, Tacy T, Teitel D, Shapiro M, Grossman W.

*American Journal of Therapeutics*. 2009;16:239-246. Jan 13. [Epub ahead of print].

### **One Year Durability of Enhanced External Counterpulsation Benefit in Improving Quality of Life and Reducing Health Care Costs\* FREE**

Lawson WE, Kennard ED, Linnemeier G, Hui JC.

Presented at the 2009 AHA Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke Conference in Washington D.C., April 23-25, 2009.

### **Does Enhanced External Counterpulsation Decrease Mortality Risk in Diabetics with End Stage Coronary Disease and Heart Failure?\* FREE**

Lawson WE, Kennard ED, Linnemeier G, Silver MA.

Presented at the 2009 AHA Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke Conference in Washington D.C., April 23-25, 2009.

### **Predictors of Hospitalization in End Stage Coronary Disease: The Effect of Enhanced External Counterpulsation\* FREE**

Lawson WE, Kennard ED, Linnemeier G, Hui JC.

Presented at the 2009 AHA Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke Conference in Washington D.C., April 23-25, 2009.

### **Peripheral Endothelial Function is a Primary Clinical Target for Enhanced External Counterpulsation in Patients With Refractory Angina**

Braith RW, Casey DP, Beck DT, Nichols WW, Choi CY, Khuddus MA, Conti CR.

*Journal of the American College of Cardiology*. 2009 Mar;53(10 Suppl A); (1054-276).

### **Promotion of Coronary Collateral Growth by External Counterpulsation in Patients with Coronary Artery Disease**

Gloekler S, de Marchi SF, Rutz T, Meier P, Wustmann K, Rimoldi SF, Togni M, Seiler C.

*Journal of the American College of Cardiology*. 2009 Mar;53(10 Suppl A);(1050-126).

\* Receive a free copy of the complete presentation by email. Email your request to [ksmig@vasomedical.com](mailto:ksmig@vasomedical.com).