

EECP® Newsletter

Updating our clinical knowledge on an evidence-based therapy

VOLUME 2, ISSUE 2



EECP® AS AN EFFECTIVE TREATMENT OF HEART FAILURE

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Epidemiology of Heart Failure

There are 5.7 million heart failure (HF) patients in the United States, 10 million in Europe and 20 million in Asia. In the US, 670,000 new patients are diagnosed with HF, with 12-15 million office visits and 6.5 million hospital days each year. In the United States, the total inpatient and outpatient costs for HF in 2005 were approximately \$37.2 billion with an additional \$3 billion spent annually on HF treatment drugs. (*The AHA Heart And Stroke Statistical 2009 Update (2009 Update); European Heart Journal, doi:10.1093/eurheartj/ehi205; Statistics by Country for Congestive Heart Failure, http://www.wrongdiagnosis.com/c/congestive_heart_failure/stats-country.htm*)

Definition of Heart Failure

Heart failure (HF) is a clinical syndrome resulting from any structural or functional disorder that impairs the ability of the ventricles to fill or eject blood to satisfy the metabolic needs of the body. Heart failure patients may have the symptoms of breathlessness, dyspnea or fatigue, either at rest or during exercise, or fluid retention that may lead to pulmonary congestion and peripheral edema. The most common causes of HF are coronary artery disease, hypertension, dilated cardiomyopathy, and valvular heart disease.

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VASOMEDICAL UNVEILS NEW PATIENT MANAGEMENT PRODUCTS AT AHA



EZ ECG™ Monitor

Taking care of a patient doesn't end at the doctor's office. It is important for some cardiac patients to monitor their ECG and heart rate at home as well. For those patients and today's health conscious society as a whole, Vasomedical offers four new FDA cleared and CE marked patient management products, specially designed to

help monitor fragile cardiac, pulmonary and renal disease patients daily at home.

Vasomedical is proud to introduce a portable, easy to use personal ECG monitor, the EZ ECG™ monitor. Checking or monitoring a patients SpO₂, pulse rate and perfusion index has never been easier or more



EZ O₂™ Finger Oximeter

affordable. Vasomedical also offers lightweight, compact, finger pulse oximeters for quick and accurate measurements in the EZ O₂™ finger oximeter, the EZ O₂™ adult/ pediatric finger oximeter, and a comfortable wrist oximeter for patients that require long-term monitoring, the EZ O₂™ wrist oximeter.



EZ O₂™ Wrist Oximeter



HIGHLIGHTS

Current Issue

- ♥ Learn about how EECP can treat heart failure, billing for EECP and its cost-effectiveness
- ♥ Vasomedical Unveils New Patient Management Products At AHA

Next Issue

- ♥ What you should tell your patients about EECP®

NEWS AND EVENTS

- ♥ Read what physicians and real patients have to say about EECP® on the boards at www.eecpforum.com
- ♥ Vasomedical participates in the AHA Scientific Sessions in Orlando, FL November 14-18

Treatment of Heart Failure

The objectives of treatment are to provide symptomatic improvement, prevent transition of asymptomatic cardiac dysfunction to symptomatic HF, and reduce ER visits, hospitalizations and mortality. Pharmacological therapy is used to treat hypertension, hyperlipidemia and diabetes. Medical devices such as pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization therapy are used to correct abnormal conduction and arrhythmia; ultra-filtration for fluid overload, and ventricular assist devices or artificial heart as a last resource for circulatory assistance.

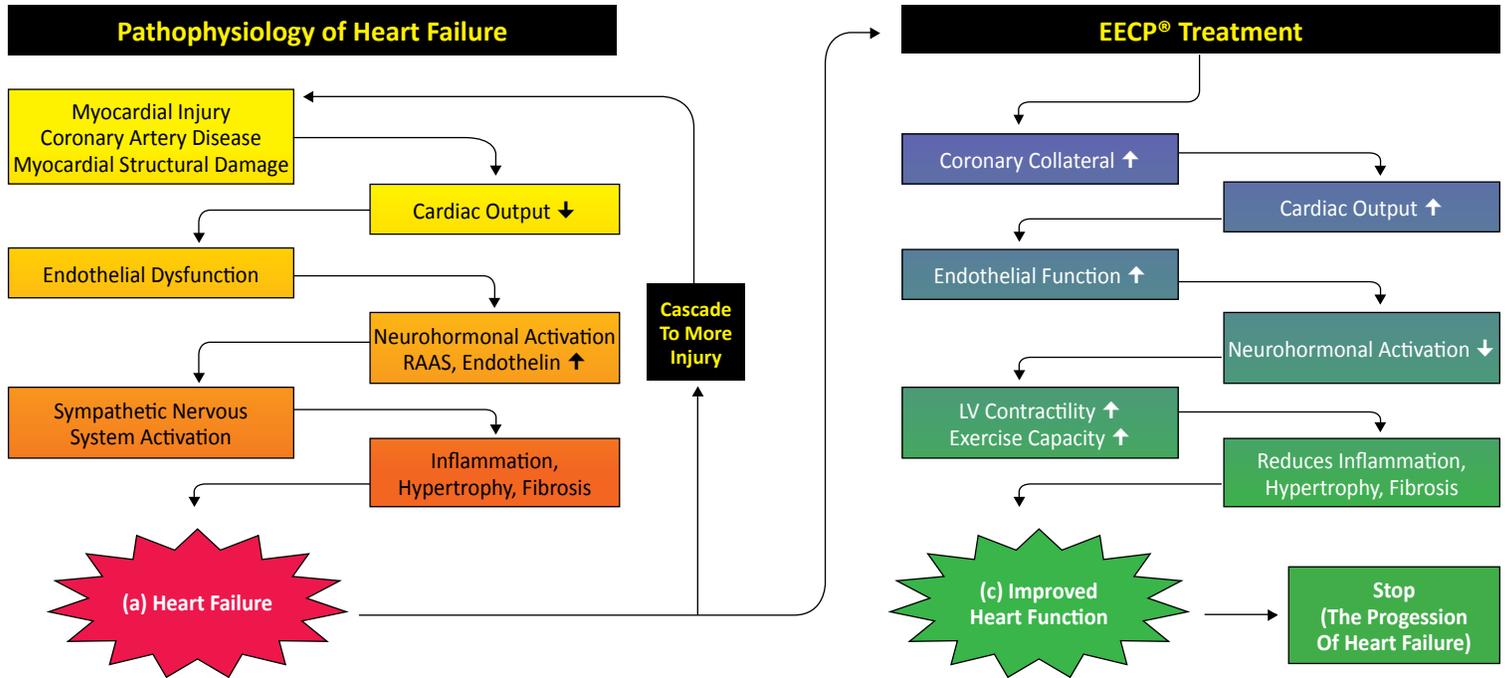


Figure 1: (a) the pathophysiology of heart failure starting with some form of injury to the heart muscle and cascading down to heart failure and leading back to more myocardial injury; (b) EECP® stops the path back to more myocardial injury; and (c) improved heart function after EECP® treatment in reducing the negative remodeling effects of heart failure.

Currently there are few effective therapies for heart failure partly because it is not a single organ disease but a systemic disease, as illustrated in Figure 1, the pathophysiology of heart failure. Heart failure usually starts with some form of injury to the muscle of the heart due to coronary artery disease or some form of infection, reducing the ability of the heart to perform effectively to eject blood, decreasing blood flow velocity leading to endothelial dysfunction, activating the neurohormonal renin-angiotensin-aldosterone system (RAAS) and sympathetic nervous system, promoting further vessel constriction. When the body demands the heart to pump out more blood to satisfy its metabolic needs, the heart becomes hypertrophied and fibrosis develops. This induces an inflammatory reaction promoting smooth muscle cell proliferation and migration, building atherosclerotic plaque leading to further injury of the heart. This condition continues and cascades to worsening of the heart failure.

Enhanced External Counterpulsation (EECP) is the only treatment methodology that deals with every aspect of the deteriorating effects leading to heart failure. There is ample scientific evidence that EECP therapy promotes coronary collateral circulation providing more blood supply to ischemic regions of the heart to improve cardiac output. The improved cardiac function increases blood flow velocity and shear stress on the endothelium, thereby promoting the release of circulating endothelial progenitor cells and improve endothelial function and vascular tone. This in turn reduces neurohormonal activation, proinflammatory cytokines, arterial wall stiffness and intimal hyperplasia, thereby lowering vascular resistance and blood pressure, reversing the deteriorating systemic effects leading to HF.

The beneficial mechanisms of action of EECP therapy are illustrated in the positive results from a randomized, controlled clinical trial known as PEECH™ (Prospective Evaluation of EECP® in Congestive Heart Failure). In this trial, 187 mild-to-moderate HF patients with NYHA II or III classification were randomized into either EECP + pharmacologic therapy (PT) or PT alone. The results of PEECH™ trial showed a significant increase in the primary end point with 35% of EECP treated patients achieving a 60 seconds or more increase in exercise duration versus 25% in the PT control group at 6 months ($p < 0.016$) post treatment. The trial also demonstrated significant improvements in favor of EECP therapy on several important secondary endpoints, including improvements in exercise duration, symptom status and quality of life. Measures of change in peak oxygen consumption were not statistically significant in the overall study population, though a trend favoring EECP therapy was present in the early follow-up period. Patients in the trial who had an ischemic etiology (i.e. pre-existing coronary artery disease) demonstrated a greater response to EECP therapy than those who had an idiopathic (non-ischemic) etiology. (*J Am Coll Cardiol* 2006;48:1198–205).

A second paper resulting from the PEECH™ trial was published in 2006, focusing on a prespecified subgroup analysis of patients age 65 and over (*Congestive Heart Failure*. 2006 Nov-Dec;12(6):307-311). This analysis demonstrated a statistically positive response on both co-primary endpoints of the trial in patients receiving EECP therapy versus those who did not, i.e. a significantly larger % of patients undergoing EECP® therapy met or exceeded prespecified thresholds of 60 seconds in exercise duration and the % of patients with at least 1.25 ml/min/kg increase in peak volume of oxygen uptake (VO_2) at 6 month follow-up. Moreover, patients age 65 and older who received EECP therapy demonstrated the greatest improvement in exercise duration, peak oxygen consumption and functional class (symptom status) compared with those who did not receive EECP® therapy.

Coverage Policy for Heart Failure

In February 1999, the Centers for Medicare and Medicaid Services (CMS) issued a national coverage policy for the use of EECP in the treatment of 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 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 states which create excessive risk.

Since 70-80% of heart failure patients suffer from ischemic heart disease, they may be eligible for coverage under the current guidelines, as long as they meet the angina criteria and their angina is listed as the primary indication for EECP therapy. Patients suffering from angina often have similar symptoms to those suffering from ischemic HF. Exertional angina pectoris or its equivalents are often present in patients with ischemic left ventricular dysfunction. Angina or angina equivalent symptoms do not have to be the only diagnosis, but it must be the reason for which EECP therapy is being prescribed. Ischemic heart failure can be a co-diagnosis. Data collected and published from the International EECP® Patient Registry™ (IEPR) at the University of Pittsburgh Graduate School of Public Health on 8,000 patients treated with EECP® shows that approximately one-third of angina patients treated with EECP also have a history of HF and 70% to 80% have demonstrated positive outcomes from EECP therapy (*Cardiology*. 2001;96(2):78-84). These HF patients with refractory angina were covered by CMS and third party insurance.

Cost Effectiveness

As our society ages, and the mortality rate for patients suffering from myocardial infarction decreases, the number of patients with heart failure will increase at a much faster pace, placing much more stress on the healthcare system. In 2007, Dr. Ozlem Soran and colleagues published a paper on the “Impact of EECP Treatment on Emergency Department (ED) Visits and Hospitalizations in Refractory Angina Patients with Left Ventricular Dysfunction” (*Congestive Heart Failure*. 2007:36-40). The clinical outcomes, number of all-cause ED visits, and hospitalizations within the 6 months before EECP therapy were compared with those at 6-month follow-up in 450 patients with LV dysfunction treated with EECP therapy for refractory angina.

The mean number of ED visits per patient decreased from 0.9 ± 2.0 pre-EECP to 0.2 ± 0.7 ($p < 0.001$), a reduction of 78%, and hospitalizations were reduced from 1.1 ± 1.7 to 0.3 ± 0.7 ($p < 0.001$) at 6 months, a reduction of 73%. There were 1,106,000 hospital discharges for HF in 2006 (data from U.S. National Hospital Discharge Survey) and 3,390,000 ED visits for HF (U.S. National Center for Health Statistics Report No.8, 2008). The average cost for an ED visit in 1998 has been estimated to be \$12,400 per admission (*Heart Lung*. 1999 Mar-Apr;28(2):102-9). A reduction of 73% or 1 million or more admissions could save the health care budget \$10,000,000,000, a welcome reduction in this era of high health care costs.

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: Paul Persaud, Marketing Manager at ppersaud@vasomedical.com.

RECENT PUBLICATIONS & PRESENTATIONS

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).

Treatment Options for Refractory Angina Pectoris: Enhanced External Counterpulsation Therapy

Ozlem Soran, MD, MPH, FESC

Practitioner. Current Treatment Options in Cardiovascular Medicine 2009, 11:54–60

Enhanced External Counterpulsation Promotes Growth Cytokines-Mediated Myocardial Angiogenesis In A Porcine Model Of Hypercholesterolemia

Luo Jing-Yun, Wu Gui-Fu, Xiong Yan, Chen Guo-Wei, Xie Qiang, Yang Da-Ya, He Xiao-Hong, Zhang Yan, Liu Dong-Hong, Wang Kui-Jian, Ma Hong, Zheng Zhen-Sheng And Du Zhi-Min

Chinese Medical Journal 2009;122(10):1188-1194

Assessment Of The Effect Of External Counterpulsation On Myocardial Adaptive Arteriogenesis By Invasive Functional Measurements — Design Of The Arteriogenesis Network Trial 2

Nikolaos Pagonas, Wolfgang Utz, Jeanette Schulz-Menger, Andreas Busjahn, Jan Monti, Ludwig Thierfelder, Rainer Dietz, Volker Klauss, Michael Gross, Ivo R. Buschmann, Eva-Elina Buschmann And On Behalf Of The Arteriogenesis Network

International Journal of Cardiology (2009), doi:10.1016/j.ijcard.2009.05.050

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