

INTRODUCTION TO EECP[®] THERAPY

Vasomedical EECP[®] Therapy

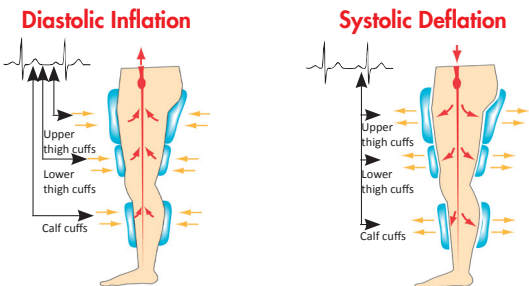
Vasomedical EECP[®]

is an FDA cleared, Medicare approved, non-invasive medical therapy for the treatment of stable and unstable angina, congestive heart failure, acute myocardial infarction, and cardiogenic shock. Hemodynamically, EECP[®] Therapy improves cardiac output, increases circulation, recruits and develops new collaterals. It also increases shear stress on the endothelium, improving endothelial function, reduces circulating inflammatory markers and arterial stiffness, while also inhibiting smooth muscle cell proliferation and migration. More than 150 peer-reviewed papers have been published demonstrating EECP[®] to be safe and effective in the treatment of angina and chronic heart failure.



EECP[®] THERAPY DELIVERY

The EECP[®] system consists of three sets of inflatable pressure cuffs wrapped around the calves and the lower and upper thighs, including the buttocks. In synchronization with each cardiac cycle, obtained with an integrated 3-lead ECG, the cuffs are sequentially inflated from the calves to the buttocks during diastole to produce an arterial retrograde flow towards the aortic root to increase coronary blood flow. EECP[®] simultaneously increases venous return to raise cardiac output. The cuffs are deflated simultaneously before the onset of systole to provide an empty vascular space, reducing systemic vascular resistance in the lower extremities to receive blood ejecting from the heart, significantly reducing the workload and oxygen demand of the heart.





PATIENT SELECTION

EECP® Therapy is primarily used as a non-pharmacologic outpatient treatment for patients with chronic stable angina (chest pain, atypical pain, shortness of breath, fatigue, and cough) as well as the symptoms of heart failure. Patients with severe, diffuse coronary atherosclerosis and persistent angina, or significant silent ischemia burden, such as elderly patients and those with diabetes, challenging coronary anatomies, or debilitating heart failure, renal failure, or pulmonary disease, have also been shown to derive benefit from EECP® Therapy. EECP® Therapy has also been shown to be effective in relieving angina symptoms in patients with Cardiac Syndrome X. Benefits of EECP® have also been determined in the management of angina in the elderly, angina patients with left main disease, and in patients with mild refractory angina (CCS Class II). EECP® Therapy is equally effective in reducing angina symptoms in patients with or without diabetes, and in patients with all ranges of body mass index.

EECP® Therapy has also been shown to improve exercise capacity in heart failure patients with NYHA Class II/III and in exercise peak oxygen consumption in older patients with heart failure. EECP® Therapy has also been demonstrated to be equally effective in providing symptomatic benefits in angina patients with either systolic or diastolic heart failure. For patients with left ventricular dysfunction, EECP® Therapy has been shown to sustain the initial benefits for up to 3 years.

CONTRAINDICATIONS

EECP® Therapy should not be used for the treatment of patients with:

- Arrhythmias that interfere with machine triggering,
- Bleeding diathesis,
- Active thrombophlebitis,
- Severe lower extremity vaso-occlusive disease,
- Presence of a documented aortic aneurysm requiring surgical repair,
- Pregnancy.

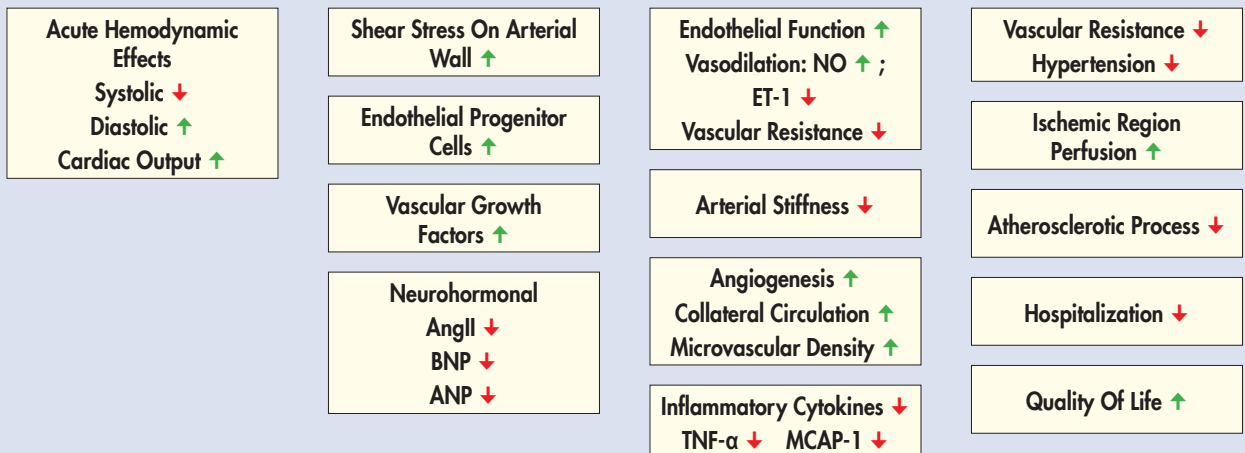
MECHANISMS OF ACTION

There is evidence demonstrating improved endothelial function via the hemodynamic effects by the increased shear stress acting on the arterial wall, reducing arterial stiffness and providing protective effects against inflammation, inhibiting intimal hyperplasia and the atherosclerotic process.

PRECAUTIONS

- Patients with blood pressure higher than 180/110 mmHg should be controlled prior to treatment with EECP®.
- Patients with a heart rate more than 120 bpm should be controlled prior to treatment with EECP®.
- Patients at high risk of complications from increased venous return should be carefully chosen and monitored during treatment with EECP®. Decreasing cardiac afterload by optimizing diastolic augmentation may help minimize increased cardiac filling pressures due to venous return.
- Patients with clinically significant valvular disease should be carefully chosen and monitored during treatment with EECP®. Certain valve conditions, such as significant aortic insufficiency, or severe mitral or aortic stenosis, may prevent the patient from obtaining benefit from diastolic augmentation and reduced cardiac afterload in the presence of increased venous return.

Acute EECP® Effects → Mechanisms → Pathophysiological → Clinical Outcomes



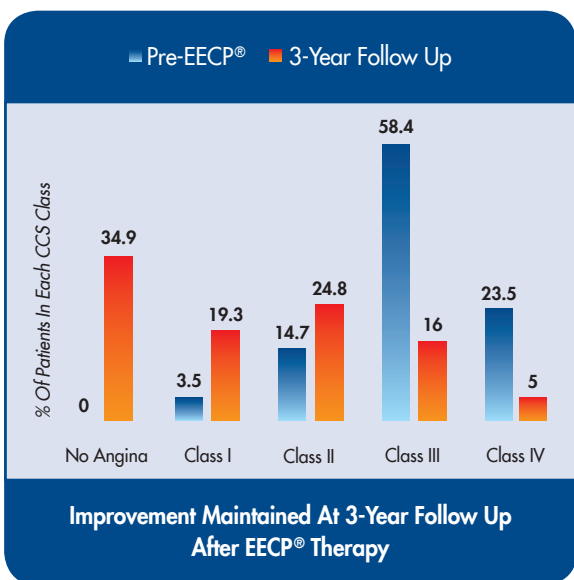
There is also evidence that EECP® Therapy triggers a neurohormonal response that induces the production of growth and vasodilatation factors, which together with the increased pressure gradient created across the occlusive site during EECP® Therapy, promotes recruitment of new arteries, while dilating and normalizing the function of existing blood vessels. The collaterals bypass stenoses and increase blood flow to ischemic areas of the heart, leading to improved clinical outcomes.

SUGGESTED TREATMENT PROTOCOL

The treatment is administered to patients on an outpatient basis, usually in daily one-hour sessions, five days per week over seven weeks for a total of 35 treatments. EECP® is equally effective if it is given twice daily, each with one-hour session separated by a minimum of 30-minutes break for a total of three and a half weeks. The procedure is well tolerated and under this suggested protocol, approximately 75% of patients experience relief of symptoms caused by their coronary artery disease following the course of treatment.

CLINICAL EVIDENCE

Since 1992, there have been more than 150 papers published in peer reviewed medical journals demonstrating EECP® Therapy as a non-invasive, safe, low-cost and highly effective treatment for patients with coronary artery disease. There are 8 randomized controlled trials (RCT) documenting the clinical outcomes and mechanisms of action of EECP® Therapy. The most well-known RCTs were the Multicenter Study of EECP® (MUST-EECP) in the treatment of patients with angina pectoris and Prospective Evaluation of EECP® in Congestive Heart Failure (PEECH™) study. There is also a subgroup study analyzing data from the PEECH™ trial for heart failure patients age 65 or older. For a complete Bibliography or Synopsis of the Clinical Studies for EECP® Therapy, please visit: www.vasomedical.com.



INTERNATIONAL EECP® PATIENT REGISTRIES

There are two International EECP® Patient Registries, (IEPR I with 5,000 patients and IEPR II with 2,500 patients) which were maintained at the Epidemiology Data Center of the University of Pittsburgh and completed in July 2001 and Oct 2004 respectively. This determined the patterns of use, safety and efficacy of EECP® for a period up to 3 years post treatment. Data collected were patients' demographics, medical history, CAD status, quality of life, CCS Classification, medication, angina frequency and adverse clinical events before EECP®, post EECP®, and during follow-up periods.

REIMBURSEMENT

Currently, the Centers for Medicare and Medicaid Services (CMS) and many commercial third-party insurance payers have provided coverage of EECP® treatment 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 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.

Patients with a primary diagnosis of heart failure, diabetes, peripheral vascular disease, etc. are also eligible for reimbursement under the current coverage policy, provided the primary indication for treatment with EECP® Therapy is angina or angina equivalent symptoms and the patient satisfies other listed criteria.



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SEARCHING FOR TREATMENT?



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