



was observed to be a safe and effective treatment for angina in patients with severe LVD who were not considered good candidates for revascularization by coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI). Importantly, there was a significant reduction in Canadian Cardiovascular Society (CCS) angina class and quality of life improved approximately 70 percent for all patients completing treatment. The major cardiovascular event (death, MI, CABG, PCI) free survival rate was 77 percent at one-year follow up.⁹ Considering the high risk of comorbidity in this cohort, these results supported the initiation of a pilot study.

A multi center feasibility study in which stable heart failure patients (NYHA class II - III) with LVEF < 35% were treated with 35 one-hour sessions of EECP therapy over a seven-week period, and then were followed over a six-month period, demonstrated that EECP was safe and well-tolerated in this group of patients.^{10,11} In addition, EECP was associated with significant improvements in exercise capacity as measured by peak oxygen uptake and exercise duration, and in quality of life at one-week and six-months following EECP treatment. Although safety was the primary endpoint of this feasibility study, the efficacy results suggest that EECP can increase peak oxygen uptake, and improve exercise capacity and functional status as well as the patient's quality of life, for both the short-term and long-term (six months) after the completion of a course of EECP therapy. Study subjects benefited from EECP to a similar degree, regardless of whether the etiology of their heart failure was ischemic or non-ischemic.

To test the hypothesis that EECP may have beneficial effects on LV function in patients with heart failure, Gorcsan et al.¹² studied the effects of EECP on LV function in patients with NYHA Class II or III heart failure with an LVEF < 35%. EECP was associated with a significant improvement in LV function, as measured by increases in both PAMP (pre-load adjusted maximal power – a normalized measure of contractile force) and LVEF, as well as a significant decrease in heart rate. Importantly, these beneficial effects were sustained six months after EECP therapy. Thus, preliminary data shows that EECP improves LV function in heart failure patients and may be a useful adjunct to medical therapy in these patients.

Currently, a multi center, prospective, randomized, controlled clinical trial (PEECH) is on-going to verify the efficacy of EECP as an adjunctive therapy in the management of patients with chronic stable heart failure. In addition, in February 2003 the collection of data on heart failure patients was initiated in Phase 2 of the IEPR.

FDA Cleared Indications:

The established indications of stable or unstable angina pectoris, acute MI and cardiogenic shock were recently expanded to include congestive heart failure.

Which Group of Heart Failure Patients may Benefit from EECP?

1. Patients with stable heart failure, NYHA Class II and III (patients with any evidence of decompensation should not be treated until they are stable with the use of medical therapy).
2. Patients with ischemic or idiopathic cardiomyopathy.
3. Patients in stable condition with manageable peripheral edema, (i.e., less than 1+ edema).
4. Patients with LVD (EF <35%).
5. Patients with heart failure and other co-morbid states (i.e., diabetes, pulmonary disease) that increase their surgical risk.

Managing EECP Heart Failure Patients

1. Verify that the patient is in stable condition – auscultate lung sounds, check weight and the degree of peripheral edema.
2. Obtain vital signs – blood pressure, heart rate and rhythm, respiratory rate and character.

3. Obtain baseline pulse oximetry measurements and record oxygen saturation.
4. Initiate EECP treatment – achieve full treatment pressure (260-280 mmHg) within 5 minutes of applying pressure.
5. Record during-session plethysmography tracings every 20 minutes – evaluate and adjust inflation/deflation timing.
6. Record oxygen saturation every 20 minutes. Discontinue the treatment if oxygen saturation decreases by 3 percent or more from the day's baseline measurement.
7. Observe the patient throughout the treatment hour. Patients should never be left unattended while receiving EECP therapy.
8. Repeat physical assessment and vital signs before the patient leaves the treatment area.
9. Report all changes in the patient's condition to the physician before initiating or continuing treatment.

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Enhanced External Counterpulsation (EECP) and its Role in Heart Failure Treatment

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What is Heart Failure?

Heart failure can be defined as the inability of the heart to meet the metabolic demands of the tissues at physiologic right and left filling pressure at rest or during activity. The term heart failure doesn't describe a single "disease" but rather a constellation of signs and symptoms that include shortness of breath, overwhelming fatigue and edema. It is a clinical syndrome characterized by ventricular dysfunction associated with reduced exercise tolerance, incidence of arrhythmias, high morbidity and decreased quality of life. The syndrome can include symptomatic left ventricular dysfunction (LVD), isolated systolic dysfunction, or heart failure with preserved systolic function. Appropriate diagnosis and treatment can impact mortality, morbidity, symptoms, disease progression and quality of life.

digoxin, and more recently, beta blockade, biventricular pacing and ICD implantation. The MADIT II trial revealed that the prophylactic use of an ICD in patients with a previous myocardial infarction (MI) and reduced left ventricular ejection fraction (LVEF) significantly reduced the risk of death. However, ICD therapy was associated with a higher rate of new or worsened heart failure than was conventional therapy. The patient population that could benefit from prophylactic treatment is large; if a meaningful number of these patients receive an ICD prophylactically, it will contribute to the increase in the number of newly diagnosed heart failure patients.

Despite the improvements in the management of heart failure the need for new treatment modalities remains, urging scientists to investigate new technologies.

What is the Role of EECP in Heart Failure Treatment?

Enhanced external counterpulsation has been shown to improve both angina and stress myocardial perfusion in patients with coronary artery disease.¹⁻⁶ However, a primary concern is that the increased venous return resulting from EECP may precipitate pulmonary edema in angina patients with severe LVD or an exacerbation of heart failure in angina patients with a history of heart failure. As with beta blockers in the treatment of heart failure, the role of EECP has evolved over time such that it was recently cleared by the FDA for the treatment of heart failure.

The Path Leading to the Treatment Option for Heart Failure

Initially, the safety and efficacy of EECP was evaluated in patients with angina and severe LVD (EF <35%).^{7,8} At initiation of treatment, 57 percent of patients had a history of congestive heart failure, 88 percent a history of MI. The outcomes of EECP treatment were followed for six months in patients enrolled in the International Enhanced External Counterpulsation Patient Registry (IEPR), an international multi center study of EECP for the treatment of patients with chronic angina. EECP

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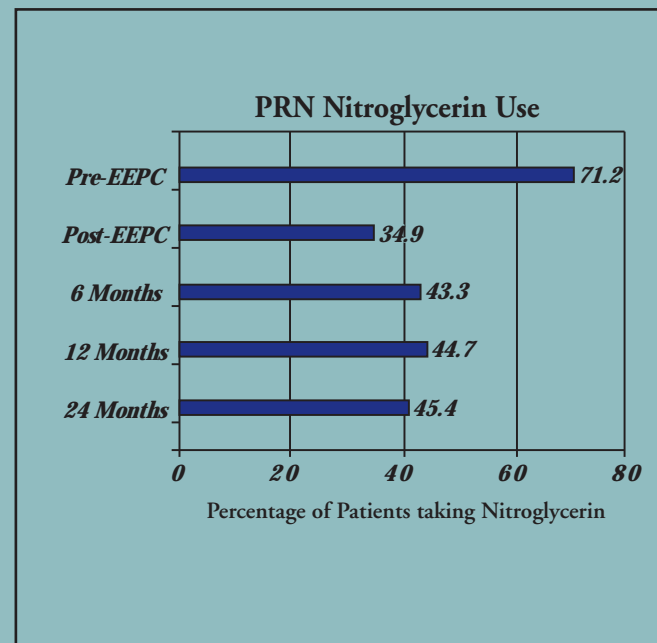
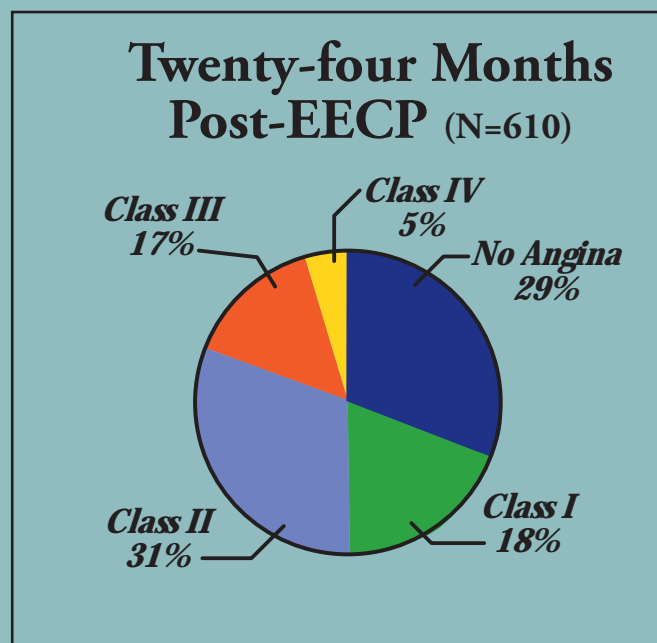
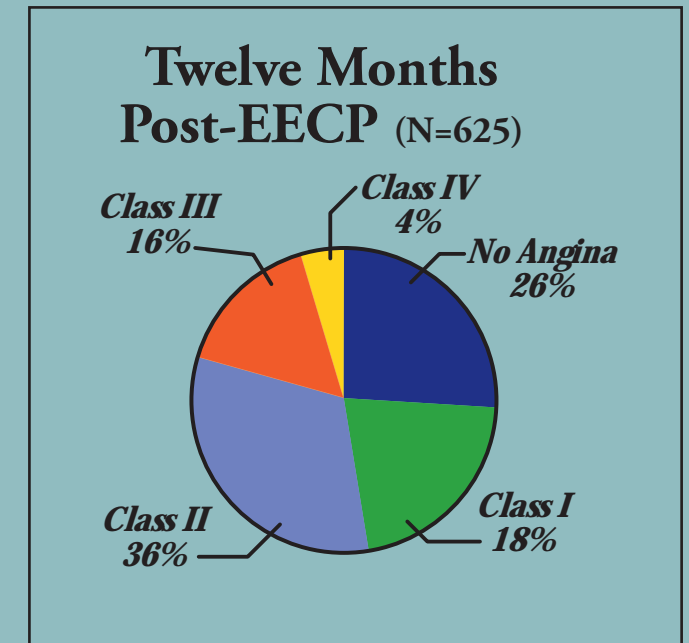
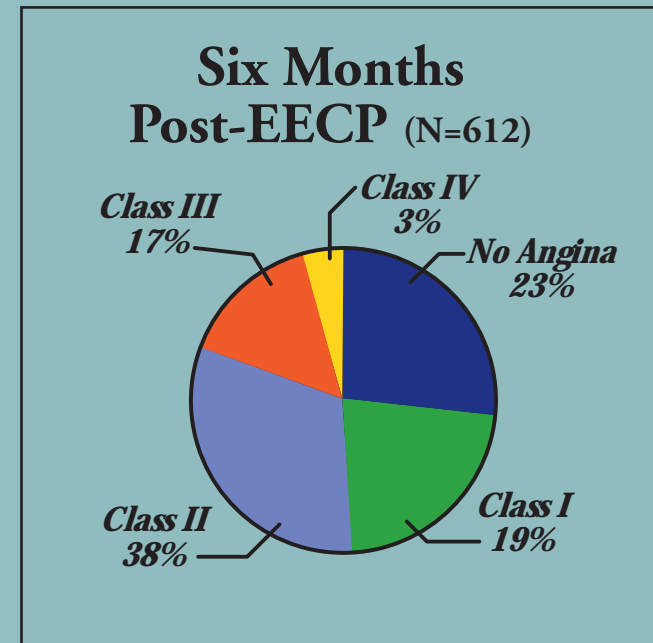
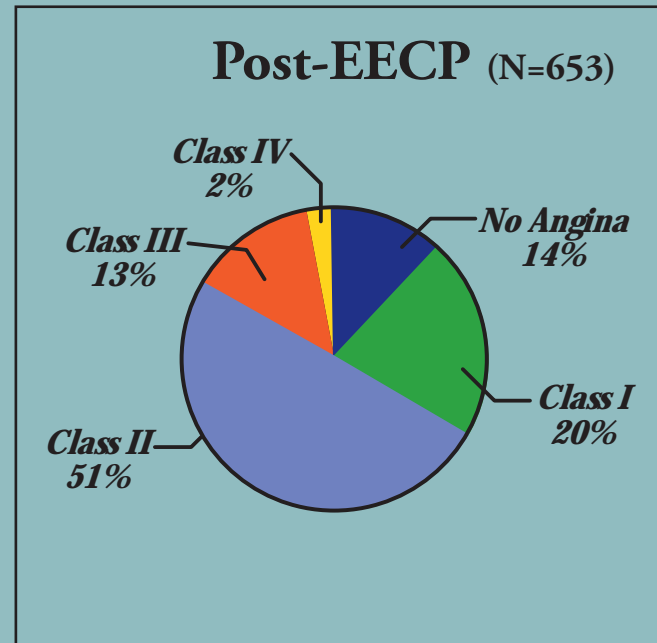
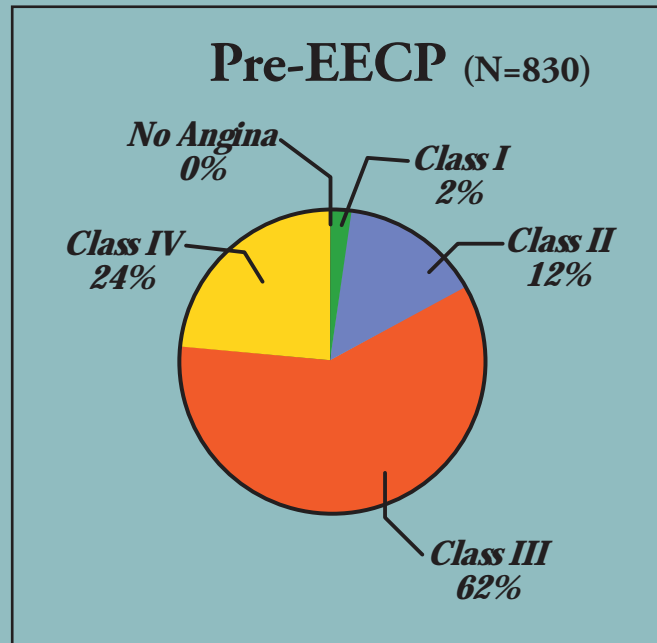
Significance of Heart Failure

Heart failure has reached epidemic proportions in the U.S., affecting over 5 million patients with 550,000 new cases reported each year. As clinicians have become increasingly adept at ameliorating the immediate consequences of acute coronary syndromes, the population of patients with heart failure has increased steadily and has been associated with a dramatic increase in healthcare costs. Furthermore, heart failure is a disease of the aged. Aging of the population in and of itself has substantially increased the incidence of heart failure. Heart failure accounts for 5 to 10 percent of all hospital admissions, and is the most frequent cause of hospitalization in the elderly. The impact of heart failure is felt in both the U.S. and around the world as its incidence continues to rise.

Heart Failure Treatment

Therapy for chronic, stable heart failure is directed at reducing symptoms, promoting clinical stability and slowing disease progression. Outpatient treatment of heart failure includes diuretics, angiotensin converting enzyme (ACE) inhibitors,

EECP Therapy: Duration of Clinical Benefit



EECP Therapy: Duration of Clinical Benefit

The International EECP Patient Registry (IEPR) database was frozen on 1/07/03. Post-EECP, 6 month 12 and 24 month data below reflect patients who completed the prescribed course of EECP treatment (at least 35 hours) from 24 clinical sites providing at least 80% follow-up data at 24 months.

Patient Demographics

Mean age 66.0 years
 Age > 65 56.2%
 Male gender 73.9%

Medical History

Duration of CAD 10.5 years CHF 30.2%
 Prior PCI/CABG 87.1% Diabetes 42.1%
 Prior MI 67.5%

	Pre-EECP (N=830) %	Post-EECP (N=653) %	6 months (N=612) %	12 months (N=625) %	24 months (N=610) %
No Angina	-	14.2	23.0	26.2	29.3
Class I	1.8	20.2	18.6	17.8	18.4
Class II	12.2	50.5	38.6	36.2	29.7
Class III	62.5	12.7	16.7	16.3	17.2
Class IV	23.5	2.3	3.1	3.5	5.4
Improved by >=1 classes		82.7			
Improved by >=2 classes		36.7			
No increase in angina since Post-EECP			78.6	76.3	74.6
prn Nitro use	71.2	34.9	43.3	44.7	45.4

N's refer to number of patients reporting angina at these time points