# Enhanced External Counter Pulsation (EECP)

**"Natural Bypass in Coronary Artery Disease by Non-invasive Technique"**


## DR.ASHOK GOYAL, MD

**BANI PARK HOSPITAL**

**(Heart, EECP & Multispeciality)**

D-9, Kabir Marg Bani Park, Jaipur-302016

**Ph: 0141-2203864, 2203866; Fax: 2202382/ 5103866;**

**Email: bphospital@gmail.com. Web: www.bphospital.net**


## INTRODUCTION

Cardiovascular Disease affects more than 50 million people in India and is the leading cause of death for Indian men and women, accounting for nearly 1 million fatalities every year. One of the great dangers of heart disease is that it can take 10- 20 years to develop. While there are certain **genetic risk factors** that can predispose one to the development of heart disease – such as diabetes, hypertension, familial dyslipidemia, high levels of homocysteine, and auto-immune or inflammatory processes – as well as acquired lifestyle risk factors, such as smoking, improper nutrition, sedentary lifestyle, obesity, stress, and type-2 diabetes – coronary artery disease still often goes undetected until the heart and circulatory system have been seriously compromised. Therefore, an individual may experience no warning signs, not even pain, until he or she suffers a heart attack.

## Conventional Management of Heart Disease

Traditionally, strategies for managing cardiovascular disease have focused on the modification of risk factors (poor diet/nutrition, lack of exercise, smoking), medication, and surgical procedures such as angioplasty and bypass surgery, which treat the illness as a "plumbing problem" and focus on opening or bypassing blockages in the vessels of the heart. Despite these interventions, 54% of patients who receive angioplasty, 20% of patients who receive angioplasty + stent and 8% of patients who receive bypass surgery require repeat surgeries/procedures within a few years, and a significant number of people continue to suffer from frequent, severe, and disabling angina. It is clear that if we rely on these strategies alone, we will continue to fail these people.

## A Non-Invasive Strategy for the Management of Heart Disease

Enhanced External Counter Pulsation (EECP) is a completely non-invasive therapy, which causes minimal, if any, patient discomfort. Approved by the FDA (USA) and covered both by Medicare and by most major health plans in USA, a typical course of treatment of EECP costs only Rs.65,000/- to Rs.90,000/- in India. This is merely a fraction of the cost of angioplasty or bypass surgery, which can cost between rupees 1.5 lacs and 4.5 lacs. Despite the fact that many consider EECP a "low-tech" procedure, research has documented conclusively that this treatment significantly reduces mortality in the setting of acute myocardial infarction and/or cardiogenic shock. Furthermore, patients who undergo EECP use less antianginal medicines and experience fewer anginal episodes so cutting down the regular treatment cost significantly. Many patients report complete resolution of their angina. Additionally, when combined with conventional treatments, EECP will enhance their overall effectiveness.

## HISTORY OF EECP

ECP is not a new invention. In fact, the basic theory and techniques of counter-pulsation were developed more than 50 years ago by researchers at Harvard University and the Massachusetts General Hospital, USA. These scientists sought to capitalize upon well-known hemodynamic and physiologic principles, by using them in the clinical setting to improve the care of patients with cardiovascular disease.

Like any other muscle in the body, the heart depends upon a robust blood supply for the provision of oxygen and nutrients. As the coronary arteries and their tributaries penetrate and traverse the wall of the heart to deliver blood to the innermost portions of the muscle, the high pressures that are generated during systole are more than sufficient to impede, stop or even reverse the flow of blood through some of these vessels. Consequently, **unlike the rest of the body, the heart receives approximately 80% of its blood supply during *diastole*,** while it is at rest. The amount of oxygen that the heart uses to sustain its work is determined by the heart rate, contractility and systolic wall tension (also referred to as "afterload").

The amount of oxygen that is supplied to the myocardium is proportional to coronary blood flow, which is determined by diastolic blood pressure and coronary perfusion pressure. Based upon these facts, it follows that **the ratio of myocardial oxygen supply to myocardial oxygen consumption is increased by lowering systolic blood pressure (systolic unloading) and/or by increasing diastolic blood pressure (diastolic augmentation). These physiologic principles are the basis for Counter-pulsation (CP) Therapy.**

The first attempts at CP utilized a femoral artery cannula, which was attached to an extracorporeal pump. The pump withdrew blood from the circulation during systole and returned it during diastole. This technique was shown to increase coronary artery blood flow and to reduce the workload and, subsequently, the oxygen consumption of the left ventricle. Unfortunately, the pumping mechanism resulted in an unacceptable amount of hemolysis, making this technique unsuitable for clinical use.

This work led to the development of an ***internal* CP device** known as the **Intra-Aortic Balloon Pump (IABP).** This device, basically a catheter with a balloon attached to its end, was inserted through the femoral artery and advanced to the descending aorta. By inflating the balloon during diastole, the IABP was shown to increase blood flow and oxygen to the heart through the coronary arteries. By deflating the balloon just before systole, both after-load and the heart's overall workload were reduced. Not only did the IABP provide immediate relief to patients whose hearts were ischemic due to diseased coronary vessels, it also stimulated both the recruitment and the development of collateral vessels around the heart, providing new and permanent pathways for the delivery of blood and oxygen.

In mid-1960's there was the development of the first ***external* CP device**. Taking advantage of the same physiology as the IABP, researchers designed a system that was extra-corporeal and completely noninvasive. This machine consisted of large, steel chambers that housed inflatable cuffs, which were part of a hydraulic circuit. The cuffs were wrapped around subject's calves, thighs and buttocks and were inflated and deflated in synchrony with diastole and systole, respectively. As observed with internal CP, the external CP resulted in increased coronary blood flow and decreased left ventricular work and oxygen consumption. Unlike internal CP, however, external CP afforded the additional benefit of increased venous return (preload). In clinical application, external CP was shown to improve survival rates for patients with acute myocardial infarction, cardiogenic shock, and angina pectoris, but the results were not obtained consistently and the technique did not gain much favor

among clinicians. In addition, these initial results were significantly overshadowed by the even more impressive successes achieved through coronary artery bypass grafting and angioplasty, as these procedures were invented and refined in the 1970s.

***The original CP used steel chambers***

***Early CP device with hydraulic circuit***

## The United States Takes Notice

A group of investigators (Lawson WE, Hui JCK, Soroff HS, *et al*) at the State University of New York at Stony Brook (SUNY) carried out a number of open-label studies with the EECP system between 1989 and 1996 using both objective and subjective endpoints. Eighteen patients who suffered from debilitating angina, despite surgical intervention and medication, received 35 one-hour sessions of EECP over a period of 7 weeks. At the end of these treatments, all eighteen patients showed improvement in angina. Results showed that

- Sixteen patients (89%) could perform their normal daily activities without symptoms
- Twelve (66%) tested completely normal on nuclear stress tests following treatment, showing that normal blood flow had been reestablished in the heart, and
- Two (11%) had stress tests that, while still abnormal, were significantly improved.
- Stress test results were unchanged in four patients (22%).

A three-year follow up study by Lawson WE, Hui JCK, Zheng ZS, *et al* showed that eleven (79%) of participants still remained symptom free. The only treatments the subjects had received during that time had been adjustments to their medications and additional EECP treatments (8 patients).

By 1995 enough of a body of research had accumulated for EECP to receive FDA approval as a treatment for chronic stable angina, cardiogenic shock, and for use during a heart attack.

**In June of 2002, the FDA approved the use of EECP for congestive heart failure.**

## The MUST-EECP Trial

For many years critics claimed that no double-blind studies existed to prove the effectiveness of ECP, but this changed in 1995 when Vasomedical Inc., USA began a large, randomized, controlled, double-blinded clinical trial called the **"Multicenter Study of Enhanced External Counterpulsation (MUST- EECP).**

Cardiologists at seven leading university hospitals, including Columbia, Yale, and Harvard, conducted research on 139 participants. Half of these patients received thirty-five real ECP treatments and the other half received thirty-five placebo treatments (cuffs squeezing only minimally while the patient lay on the treatment bed).

Patients received treadmill stress tests both before and after receiving each EECP treatment. Following treatments, the participants in the group who had received EECP were able to exercise significantly longer without symptoms or change to their ECG, had less angina symptoms, and used less nitroglycerin. This proved that they had more blood and oxygen circulating through their hearts. Both at the completion of the thirty-five-hour course of treatments and when patients were retested one year later, those who had actually received EECP continued to show sustained improvement in their ability to work and perform daily activities. They also reported less pain, more energy, greater ability to socialize, less anxiety and depression, and lower levels of angina (Arora *et al*).

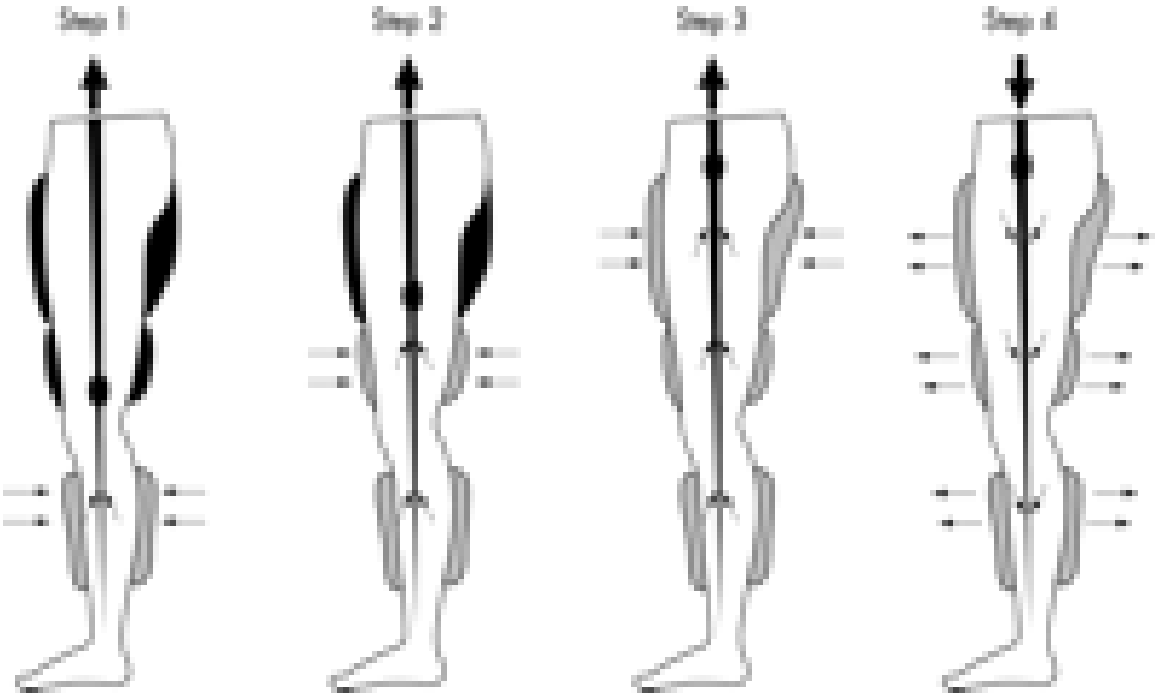
The results of the MUST-EECP study were presented at the annual Scientific Sessions of the American Heart Association in November of 1997 and the American College of Cardiology in March

of 1998. The *Journal of the American College of Cardiology*, a major peer-reviewed medical journal, published the results of the MUST-EECP trial in June 1999.

In 1999, Medicare USA began paying for EECP treatments. Since then, most major private health insurance companies have followed suit. Currently, more than 1500 physicians in the US use EECP therapy to treat approximately 49,000 patients annually who suffer from chronic angina and heart failure. With a success rate of approximately 80% and an annual growth rate of over 30%, EECP therapy is one of the fastest-growing medical procedures in USA & Europe. In India the medical fraternity had accepted the usage and benefits of EECP in recent times and started using it. It is going to make a lot of difference in the field of Preventive & Non-Invasive Cardiology.

## HOW DOES EECP WORK?

- Patients usually receive EECP treatment for 35 hours, divided into one or two 60-minute treatment sessions five days per week.
- Patients who undergo two treatment sessions in one day require rest between sessions.
- Treatment is administered on a padded table, where three sets of electronically controlled inflation and deflation valves are located. These valves are connected to adjustable cuffs that are wrapped firmly, but comfortably, around the calves, the lower thighs, and the upper thighs and buttocks.
- Patients wear special pants during the sessions to minimize the possibility of skin irritation.
- Inflation and deflation of the cuffs is triggered by the patient's ECG signal. At the onset of diastole, the cuffs inflate rapidly and sequentially, starting from the calves and proceeding upward to the buttocks at the interval of 40 milliseconds
- This increases diastolic pressure; thereby increasing coronary artery perfusion pressure and blood flow to the heart muscle.
- Compression of the veins in the lower extremities also increases the volume of blood returned to the right side of the heart (preload). Simultaneous deflation of the cuffs just prior to the onset of systole lowers peripheral vascular resistance –thereby decreasing afterload, cardiac work, and oxygen consumption – and increases cardiac output.
- The net effect of these physiologic changes is to increase the supply of oxygen to the heart, while decreasing cardiac oxygen demand.
- This result is possible because the body has its own solution to an inadequate blood supply caused by stenosed or occluded coronary arteries.
- When a coronary vessel is severely narrowed, the body's natural response is to increase the amount of blood flowing to the heart by opening up smaller branches of nearby arteries. These smaller arteries form a network of vessels known as the "collateral circulation," which can serve to create detours around points of occlusion.
- Significant obstruction in one or more coronary arteries can create a pressure difference between areas of the heart that are perfused and those that are not.
- Repeated and pulsed increases in blood pressure during diastole may stimulate both the opening and the formation of new collateral channels across this pressure gradient within the heart, resulting in increased blood supply to ischemic tissues.
- The development and enhancement of a collateral circulation is particularly important in the heart where it may be lifesaving. However, collateralization is a gradual process, and not everyone has the same ability to develop these networks.
- EECP appears to stimulate the natural process of developing collateral circulation. In addition, there are likely other, as yet unexplained, mechanisms that contribute to the long-lasting effects of EECP.



## MECHANISM OF ACTION OF EECP

There are two primary mechanisms that have been discussed in the clinical literature.

### Mechanism of Action #1:

- Raised transmyocardial pressure gradients open "latent" conduits
- Both arteriogenesis and angiogenesis occur
- Increased shear forces stimulate growth factor release, capillary sprouting and endothelial migration
- Nitric oxide levels are increased while endothelin levels diminish
- Restoring flow reserve

### Mechanism of Action #2:

- 35 hour-long periods of cardiac assist rest the myocardium
- Myocyte metabolism switches back from free fatty acid energy supply toward glucose utilization
- Neurohumoral signals are "normalized," permitting improved arterial compliance and arteriolar reactivity
- Oxygen demand is reduced as oxygen efficiency is improved

# CLINICAL BENEFITS OF EECP

## Clinical benefits:

• Improvement in peak oxygen consumption (Soran *et al*)
• Increased ejection fraction (Gorscan *et al*, Suresh *et al*, Strobeck *et al*)
• Increased cardiac output (Gorscan *et al*, Suresh *et al*)
• Decreased heart rate (Gorscan *et al*)
• Improvement in exercise times (Soran *et al*)
• Improvements in quality of life (Soran *et al*)
• Reduction in CCS angina classification immediately after therapy (Arora *et al*)
- Up to 85% decrease at least 1 class
- Up to 54% decrease at least 2 classes
• Decreased anginal episodes and nitroglycerin use (Suresh *et al*, Int. ECP Pat. Reg.)
• Improvement sustained for up to 5 years (Feldman, Lawson, Cohn *et al*)

# WHO IS A CANDIDATE FOR EECP?

Many patients have questions about whether or not they are candidates for EECP. Since it is a non-invasive and completely safe therapy, the good news is that *everyone* is a candidate for EECP.

- ECP is especially appropriate for nearly all those who suffer from heart disease.
- This includes individuals who have irregular heartbeats or pacemakers, patients who have recently undergone invasive cardiac procedures, individuals with blood clots in their legs, people who take Coumadin, and those who suffer from peripheral vascular disease.
- There is no risk that EECP can cause a defibrillator or a pacemaker to malfunction, or that this treatment will cause any irregularities in heart rhythm.
- Patients who have received recent angioplasty, surgery for stent placement, or cardiac catheterization can receive EECP without risk and can start treatments as early as one week following these procedures, when groin tenderness has subsided.
- Those suffering from poor leg circulation from peripheral vascular disease will also do well with EECP, although it may take a longer time period for them to see results, because of a smaller volume of blood in the lower extremities to pump back toward the heart.
- In addition to helping patients with heart disease, EECP is ideal for people who wish to **improve their level of cardiovascular health and fitness.**

## Are There Risks During EECP?

While there are no dangers or risks involved in receiving EECP, there are certain conditions that require caution when considering this therapy:

1. Severe aortic insufficiency
2. An abdominal aortic aneurysm greater than 5 cm
3. Malignant Hypertension
4. Deep vein thrombosis
5. Hemophilia
6. Pregnancy
7. An open leg wound
8. Superficial phlebitis

The majority of these conditions are either temporary or treatable, and ECP can be initiated once they have resolved or been treated.

# CASE HISTORIES OF EECP PATIENTS

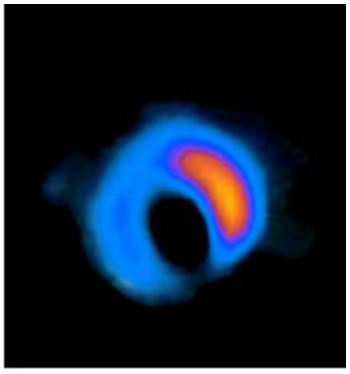
## Case History #1: Angina

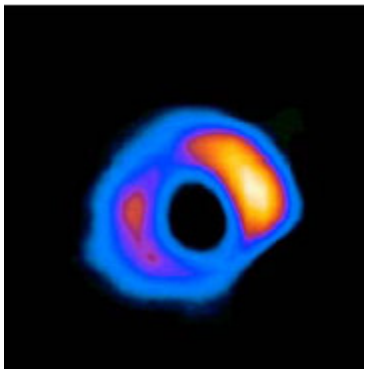
**• Patient**
27-year-old male, family history of hyperlipidemia

**• Evaluation**
- Presented with exertional angina pectoris
- 1.5-2.0 mm horizontal ST segment depression on exercise treadmill test
- 100% occlusion of mid-right coronary artery
- 100% occlusion of med-left anterior descending coronary artery 95% blockages in both proximal mid-right coronary artery and small branch of left circumflex coronary artery
- Patient not considered suitable for interventional therapy

**• Outcome**
Following 35 one-hour sessions of ECP:
- ✓ angina completely eliminated at normal levels
- ✓ post-treatment radionuclide stress testing showed marked Improvement

**Before EECP** **After EECP**





## Case History #2: Coronary Artery Disease with Diabetes

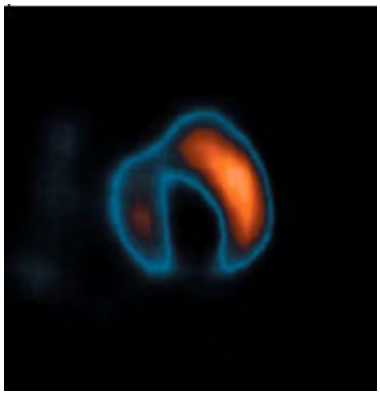
**• Patient**
72-year-old male, history of diabetes, gout, hypertension,
triple-vessel coronary artery disease (CAD)

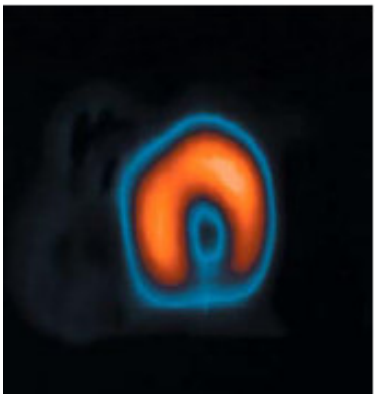
**• Evaluation**
- Presented with stable angina
- Previously declined bypass, maintained on medication
- Stress test suggested progression of CAD
- Severe hypoperfusion of inferior wall and apex with stress perfusion

**• Outcome**
Following 35 one-hour sessions of EECP:

- ✓ Post-treatment stress testing revealed marked improvement in myocardial Perfusion
- ✓ Patient showed increased exercise ability
- ✓ Chest pain symptoms were eliminated
- ✓ Patient no longer required nitroglycerin

**Before EECP** **After EECP**





## Case History #3: Congestive Heart Failure

**• Patient**
Elderly male, two previous myocardial infarctions, previous bypass surgery

**• Evaluation**
- Ischemic cardiomyopathy
- Progressive angina with minimal exertion
- Maintained on medical therapy

**• Outcome**
Following 35 one-hour sessions of EECP:
- ✓ Left ventricular ejection fraction (LVEF) increased by 80% (20% to 36%)
- ✓ Functional status and chest pain improved markedly
- ✓ Post treatment stress test showed improved cardiac perfusion and function

**Before EECP** **After EECP**