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REPORT

A Non-Invasive Alternative to
Coronary Artery Bypass Surgery

Something is definitely wrong. For weeks your complexion has grown steadily paler, you've fought constant bouts of weakness and dizziness and sometimes, for no apparent reason, your heart would suddenly race. Now, even simple actions like walking across the room brings a dull, nagging pressure in the middle of your chest accompanied by perspiration and shortness of breath.

A visit to your physician reveals a frightening diagnosis: coronary artery disease. Treatment begins immediately, but despite two cardiac catheterizations with balloon angioplasty and stenting and various prescription drugs, the chronic angina pain still won't go away. In fact, the symptoms are only getting worse. And now your doctor's latest recommendation is a terrifying one: open-heart bypass surgery.



But there is an alternative. It's a little known, non-invasive procedure that's been approved by the FDA and has been shown to alleviate angina miseries without the pain and complications associated with surgery. It's called External Counterpulsation.

What is EECP?

External Counterpulsation (EECP) is a nonpharmacologic, noninvasive, electromechanical technique approved for patients with angina pectoris- chest pain due to severe, symptomatic coronary artery disease-who have failed standard treatments and who cannot (or will not) undergo conventional procedures such as surgical bypass or angioplasty.⁴ EECP is facilitated through a pneumatic apparatus that creates a hydraulic pulse of blood flow inside the major arteries, using the vascular bed of the muscles as a pool of blood to pump. Its purpose is to boost cardiac output with no increase in cardiac work, improving cardiac efficiency and the general circulation.²



In an EECP session, the patient lies on a padded table. Three large inflatable cuffs-similar to blood pressure cuffs-are strapped around the calves, lower thighs and upper thighs. The patient's heart is monitored by an electrocardiograph machine, which, through a computer, regulates the inflation and deflation of the cuffs. During the part of the cardiac cycle when the heart is at rest (diastole), the cuffs are rapidly inflated in sequential order beginning with the cuffs at the calves and working upward. Just before systole (heart contraction), the cuffs are simultaneously deflated.⁵

The relaxation of the heart muscle is well-known to correlate electrocardiographically with the beginning of the "t-wave" representing electrical depolarization or recharging and it is the period when 85% of coronary blood flow takes place. This is the time in the cardiac cycle that is most vulnerable to obstruction by plaque that limits coronary blood flow. When the heart beats, electrically represented on the electrocardiographic trace as the "QRS complex", the EECP system relaxes, allowing the heart to pump easily into a "virtual space", with decreased vascular resistance to blood flow.

While the rest of the body receives oxygenated blood when the heart contracts, the heart muscle receives oxygen-rich blood through the coronary arteries when the heart is at rest. Therefore, the wave of pressure produced by the inflation of the cuffs when the heart is at rest increases blood flow to the heart. Deflation of the cuffs is timed so that when the heart contracts, the workload on the heart decreases as it pumps blood to other parts of the body.

When diastolic coronary flow is augmented on EECP, the arteries are presented with shearing, stretching and stress forces that are

thought to release arterial growth factors including endothelin (EGF, a polypeptide) or nitric acid (from arginine and other amino acids, felt to be a vasodilator) and possibly to have enhanced responsiveness to growth hormone and other systemic mediators. Increased VEGF (vascular endothelial growth factor) and decreased BNP (beta-natriuretic peptide) have been shown in clinical studies.⁶ Another way of looking at it is to realize that the open coronary arteries will be exposed to full augmented pressure,⁷ while the closed or narrowed artery will have lower pressure. Fluids always try to "find" a path from the high-pressure area to the low-pressure zone.⁸

Patients usually experience little or no discomfort during the procedure. Most relax and read or watch television or listen to music; some sleep. Some people are fatigued after the initial treatments, but this tends to subside within a few sessions. Patients are given snug-fitting tights during the sessions to prevent chafing, one of the main adverse effects. Improvement is usually noticed after the 15th to 20th session.

EECP is most often administered as an outpatient procedure, with each session lasting one hour. A complete course of EECP typically involves 35 hours of treatment over four to seven weeks. Two sessions can be conducted in a day.⁹

The increasing availability of EECP adds a new dimension in the treatment of coronary artery disease. According to the American Heart Association, there are more than 7.2 million people who have a history of suffering from angina. Thousands have a condition so severe that they are forced to make significant changes in their lifestyle-impaired, disabled and unable to work-or worse, unable to do simple chores like walking up stairs, carrying groceries or washing their own hair. Even getting dressed can be exhausting. These people are often forced to remain inside their homes in relative seclusion.^{10,11} Angina can become unstable; a condition that implies heightened risk of heart attack or death. EECP may be useful in those emergency conditions as well^{3,12,13,14,15} but the usual goal is to improve symptoms and decrease the hazard of subsequent cardiac events.¹⁶

Like many cardiovascular procedures that have been in use for years,^{14,17,18} few formal adequate studies had been done to demonstrate and prove the benefits of EECP. In June 1999, however, the *Journal of the American College of Cardiology* published the blinded, sham-controlled Multicenter Study of Enhanced External Counterpulsation (MUST-EECP).¹⁹ The study and its accompanying editorial, monitored by authorities on heart disease, clearly demonstrated that EECP reduces angina and extends exercise time in patients with angina. Later that year, the Health Care Finance Agency (represented by Medicare) authorized payment for the procedure-the equivalent of an official blessing-followed by two significant reimbursement increases, including an increase in 2003 of 27 percent,⁵ bespeaking the healthcare administration's confidence in the method. In April of 2000, the FDA allowed all the manufacturers who could demonstrate that their machines were fundamentally the same to market them for angina treatment-a reversal of standard policy; again, a statement of confidence in this outpatient treatment.

Proof of EECP's effectiveness has come from all over the world, most notably Japan, where a study recently published in the *Journal of the American College of Cardiology* used a program of pre- and post- treatment thallium nuclear heart scanning to methodically examine a series of patients to demonstrate the correlation between clinical improvement and stress test results.²⁰ The results showed that EECP is durable and persistent uniformly across demographic and co-morbidity (co-existing disease), with 85% to 90% showing significant improvement in symptoms.^{21,22,19,11}


Consider what this means. Many of the EECP patients are cardiovascularly-speaking the worst of the worst, having failed standard, repeated invasive surgical or balloon therapies with limiting or disabling symptoms.²³ For example, a "Class IV angina" patient can barely walk across a room without chest pain-and its attendant risk-and some even have chest pain at rest. EECP offers them a chance to be able to live better, pain free, resuming some quality of life with decreased anxiety over the next possible cardiac event.^{24,25}

Some patients and cardiologists want to visualize EECP's results by repeating a thallium stress test and nuclear heart scan. An imaging study done in Tokyo, Japan²⁰ showed consistent improvement in the patients who complete the course of therapy. Some doctors feel follow-up testing unnecessary; that the quality improvement has already been demonstrated to be due to increased myocardial perfusion in hundreds of patients.²⁶ One other reason for testing, aside from peace of mind, is to know what the post-treatment scan looks like in case of other cardiac events later.²⁷ On rare occasions, it may be necessary or desirable to have a second round of EECP treatment to attain maximal benefits.

EECP ADVANTAGES OVER SURGERY

EECP has numerous distinct advantages over surgery:^{21-24,11,41}

1. Noninvasive
2. Outpatient
3. Low risk
4. No additional medication required
5. No recuperation time required
6. No side effect
7. Patients have reported increased cognitive abilities and energy following treatment



USES IN CHINA

Contentment and quality of life

In a three-year, follow-up study, the majority of patients who received EECP therapy remained

Chinese physicians claim to have found 63 reasons to use EECP.15,17,29 Below are some of the more common ailments they use to treat with EECP.

Neuropathy, multiple types

Blood pressure³⁴

Central retinal Artery or retinal vein occlusion

Vertigo³⁵

Deafness

Stroke

Dementia

Parkinson's Disease

Erectile Dysfunction-presently under controlled study in this country and others³⁶

PVD-Peripheral vascular disease:

Anecdotal scattered reports of improvement in back pain
Rheumatic disease

Hepatitis³⁷

Kidney Disease³⁸

The Chinese believe that ECP is antioxidant³⁹

free of angina and showed persistent improvements in their thallium scans.²¹ Patients and their families have also reported noticeably greater ability to engage in daily activity. A change in the pain status and susceptibility, comportment, energy level and quality of life may be seen as soon as the tenth hour of treatment, but physicians typically suggest to patients anticipate a change after the half way mark, or 17th to 25th session. Improvement persists and continues after the treatment cycle has finished, and a final post-EECP evaluation may be undertaken 6 to 12 weeks later. If the patient is able to continue getting useful exercise, in addition to dietary and preventive medications and supplementation, many patients report ongoing improvements and a whole new lease on life.

Who qualifies?

As previously discussed, EECP is a specialized noninvasive therapy for patients with severe anginal chest pain due to coronary artery disease who cannot or will not undergo traditional surgical or invasive procedures, or in whom standard methods have failed.⁴ Patients are excluded if they have aortic valve regurgitation or insufficiency; severe limiting peripheral vascular disease, uncontrolled congestive heart failure, severe uncontrolled hypertension, cannot understand the procedure or take full dose warfarin-type anticoagulation. While undergoing treatments for coronary artery disease, at most centers patients are required to remain under the care of their own cardiologist, and a cardiologist's written prescription is required.

Why isn't EECP widely available?

EECP machines are expensive. Even though the basic technology has been around for over 20 years in its present form, it still must meet exacting standards for precision delivery of pressures and timing. As such, all electromechanical equipment has special protective devices, monitoring systems, and computer interfaces, resulting in a base price tag of \$100,000-\$250,000 for a standard installation,³ not including space and any necessary construction costs. Then there are consumables, training, and staff, so a doctor's office has to be large enough and busy enough to support an adequate patient base to keep the machine in use.

Another reason for EECP's failure to dominate mainstream medical practice is that other, more invasive procedures have more panache. Angioplasty, surgical "open-heart" bypass, laser transmyocardial revascularization, high-tech invasive procedures, mega-centers and research methods are "sexy" meaning they are highly visible and dramatic and high-tech, so they attract attention and dollars and make a medical center look important. It's a marketing phenomenon. By the same token, it's also a matter of personal accountability-this is a quick fix society and the market responds to demand.

People are willing to subject themselves to the hazards of surgery instead of going for a gentler remedy. Why? Because that is how they've been trained, that the quick and dramatic is better, even in the face of great risk of death or surgical catastrophe and the high probability of relapse. While some doctors are going back to the older approach of "let the body heal itself" using time-tested clinical acumen and intuition to make a diagnosis, in the U.S the predominant philosophy is still "more care" equals "real care."

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What other conditions may be treated with EECP?

The most common cause of congestive heart failure (CHF) is coronary artery disease. Each vessel provides a region of the myocardium with bloodflow, so when the circulation is impaired-or clots occur with local cell death-the muscle function deteriorates. Despite centuries of research and "conventional" approaches, medical treatments for CHF are often inadequate. Many patients require a heart transplant and sadly for most the post-operative prognosis is grim.^{28,29}

Because of its potential value in the treatment of congestive heart failure, EECP has recently been the focus of numerous studies, most notably the PEECH study (Prospective Evaluation of EECP in Congestive Heart Failure). According to Dr. Marc Silver, a member of the PEECH committee and author of *Success with Heart Failure*³⁰ EECP holds remarkable potential.

"It is clear that EECP is a useful adjunctive therapy for patients with coronary artery disease and early evidence suggests that it is safe and effective in patients whether or not they have a degree of heart failure. What is really exciting is whether EECP might turn out to also be a useful adjunctive therapy for heart failure itself; that is what the early results suggest and that is precisely what the PEECH trial is all about. Heart failure is our new national health care epidemic and there is only so much that can be done with medications; increasingly we are turning to other solutions."^{31,32}

In China the EECP machine is used to treat a variety of problems and studies are currently underway to further define the boundaries of its benefits.³³ For example, since EECP increases blood flow everywhere, not just to the heart, organ dysfunction present because of reduced blood flow could thus improve during EECP. Chinese physicians use arm cuffs during the procedure, further increasing blood flow to the brain. In this fashion EECP can be used in the treatment of stroke. This ability of EECP to improve blood flow in general may lead to some additional applications of EECP in this country and around the world.^{6,31}

Despite being developed almost 50 years ago, EECP is a resource that has gone overlooked for far too long. The time has come for External Counterpulsation to become a part of the generally available armamentarium for Cardiology and for general prevention and wellness.

To be referred for EECP, talk with your doctor or your cardiologist. However, many otherwise excellent cardiologists are not fully familiar with EECP, and many tend to push their patients toward experimental or invasive procedures or more drugs, so you may need to seek several opinions. If you or your physician are unaware of EECP they can find more information at:



Nicore, Inc. www.nicore.com Tampa, FL

(888) 317-3327 or inquiries@Nicore.com Nicore started marketing early in 2001, and there are more than 60 systems in use around the U.S.⁹

Vasomedical www.eecp.com, www.vasomedical.com, www.naturalbypass.com Westbury, NY (800) 455-3327(EECP). There are over 650 active installations around the world.

CardioMedics <http://www.cardiomedics.com> Irvine, CA (888) 849-0200 x 102. The original patent was issued to this company in 1986. As of this writing, there are 165 CardiAssist® machines in use around the U.S.9,40

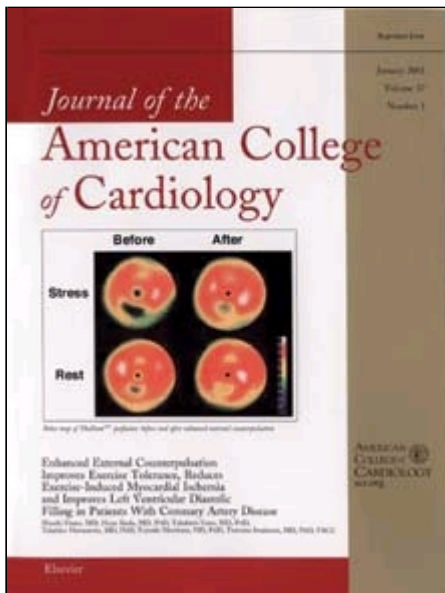
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