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REVIEW ARTICLE

Role of Enhanced External Counter Pulsation in Cardiovascular Disease

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Abstract

The heart has plays an important role in understanding the body since antiquity. In the 4thcentury B.C., the Greek philosopher Aristotle identified the heart as the most important pumping of the heart. Cardiovascular disease, one of the non-communicable diseases, has become a major public health problem in many developing countries. About two-thirds of the global estimated 14.3 million annual cardiovascular disease deaths occur in the developing world. The prevalence of cardiovascular in India increased in urban populations, andinrural populations it has almost doubled in the last decade. EECP is merged as one of the newer modalities of treatment of cardiovascular disease. EECP is a non-surgical therapy for angina, Heart disease, high blood pressure, and other conditions involving poor circulation. It is a non- invasive procedure in which long inflatable cuffs (like blood pressure cuffs) are wrapped around both of the patient's legs and works by creating collateral circulation around blocked arteries, i.e. it essentially works to create a "natural bypass" around the arteries. EECP therapy many advantages over traditional management of cardiovascular disease and the cost of EECP of therapy is much lesser when compared traditional method of treatment. It has been associated with improved exercise tolerance and myocardial perfusion, as evidenced by nuclear imaging and positron emission tomography. More research will hopefully shed additional light on the mechanism of action and verify the long-term attenuation of symptoms in patients with cardiovascular disease.

Keywords: EECP; Cardiovascular Disease; Non-Invasive Procedure; Collateral Circulation; Cost Effective.

Introduction

Cardiovascular diseases are the world's number one killers, claiming 17.5 million life a year globally. In the WHO South-East Asia Region, cardiovascular diseases cause an estimated 3.7 million deaths annually, or one fourth of all deaths [1]. While the prevalence and mortality due to Cardiovascular diseases is declining in the developed nations the same cannot be held true for developing countries. There has been an alarming increase over the past two decades in the prevalence of cardiovascular disease and cardiovascular mortality in India and other south Asian countries. India is going through an epidemiologic transition whereby the burden of communicable diseasehas declined slowly, but that of non-communicable diseases (NCD) has risen rapidly, thus leading to a dual burden. There has been a 4-fold rise of cardiovascular disease prevalence in India during the past 40 years. Current estimates from epidemiologic studies from various parts of the country indicate a prevalence of cardiovascular disease to be between 7% and 13% in

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urban and 2% and 7% in ruralpopulations. Epidemiologic studies have shown that there are at present over 30 million cases of cardiovascular disease in this country [2-3].

The Scottish Intercollegiate Guidelines Network for management of cardiovascular disease includes: education, rehabilitation, cognitive behavioral therapy, spinal cord stimulation, transcutaneous electrical nerve stimulation, left stellate ganglion block, thoracoscopic sympathectomy, **angiogenesis**, and surgical transmyocardial revascularization. In 1953, Kantrowitz demonstrated that coronary blood flow can be increased 20% to 40% by increasing diastolic blood pressure. Intra-aortic balloon pump (IABP) counterpulsation is an invasive method of increasing coronary blood flow, while enhanced external counterpulsation (EECP) is a non-invasive method. EECP therapy has been approved by the United States Food and Drug Administration (FDA) for management of cardiovascular disease [4-5].

EECP

EECP is a non-invasive treatment for coronary artery disease. EECP is the first non-surgical, non-pharmaceutical or mechanical treatment approved by the US FDA for patients with chest pain, heart failure and congestive heart failure. EECP essentially is a heart therapy without the side-effects of heart surgery. What EECP therapy does is it helps to increase blood supply throughout the body, with benefits that tend to remain for years together. EECP therapy works by creating collateral circulation around blocked arteries, i.e. it essentially works to create a "natural bypass" around the arteries [6].

Enhanced External Counter-pulsation EECP is a non-surgical therapy for angina, Heart disease, high blood pressure, and other conditions involving poor circulation. EECP is a mechanical procedure in which long inflatable cuffs (like blood pressure cuffs) are wrapped around both of the patient's legs. EECP has two potentially beneficial actions on the heart. EECP, effectively, "pumps" blood into the coronary arteries. Second, by its deflating action just as the heart begins to beat, EECP creates something like a sudden vacuum in the arteries. The EECP pumping console then rapidly inflates and deflates the leg cuffs in time with the heartbeat [7].

Indications

- Had coronary artery bypass (CABG) or stents placed in the coronary arteries with ongoing angina.
- Had no prior bypass or stenting but continue to suffer from angina
- Chronic stable angina
- Coronary artery disease
- High blood pressure
- Congestive heart failure
- Myocardial infarction
- Patients who have suffered myocardial infarction and had angioplasty or bypass surgery but continue to suffer from chest pain or other symptoms
- Patients contraindicated for angioplasty or CABG.
- Cardiomyopathy
- Patients who are looking for a natural alternative to bypass surgery or an alternative to angioplasty because they have already undergone these surgeries in the past and their conditions have recurred.
- Diabetic patients with poor blood circulation
- Renal Hypertension
- Cerebral arteriosclerosis / Thrombosis / embolism
- Chronic Fatigue (tiredness) syndrome

Contraindications

- Congenital heart disease
- Valvular disease
- Pacemaker
- Hemorrhage
- Atrial fibrillation
- Pulmonary hypertension
- Severe elevated blood pressure
- Heart rate greater than 120 beats per minute

ECPP Program Overview

Pre-EECP Treatment

Before beginning EECP, you should get a physician referral. Schedule your pre-treatment appointments, which include: Nursing assessment, Stress test, Orientation to procedures and equipment

Preparations before the Treatment

- Wear tight-fitting elastic pants. This is to prevent skin irritation or abrasion.

- Avoid ingesting food for 2 hours before the treatment
- Empty your urinary bladder before starting the session.
- If you are taking any diuretic medication, avoid taking it before the treatment.
- Continue your regular medication as prescribed by your physician [8,9].

Procedure

In EECP, 3 air cuffs are placed on each leg one on the calf, one on the lower thigh, and one on the upper thigh. The patient lie's on a table and is connected to an electrocardiogram (ECG) monitor. The ECG measures heart's electrical activity and the cuffs inflate and deflate in response to these signals. When the heart relaxes between heartbeats (the period known as diastole), the 3 cuffs rapidly inflate. This propels blood back to the heart. The cuffs quickly deflate just before the next heartbeat. The cuffs are timed to inflate and deflate based on the patient's electrocardiogram. During the inflation portion of the cycle, the calf cuffs inflate first, then the lower thigh cuffs and finally the upper thigh cuffs. A pressure monitor controls inflation, and the cuffs are inflated to about 200 mmHg. This inflation/deflation cycle occurs about 60 to 80 times per minute during an EECP session. Sessions last approximately 1 to 2 hours and are scheduled once a day. A full course of EECP treatment lasts 5 days a week for 7 weeks, with about 35 hours of treatment time [10].

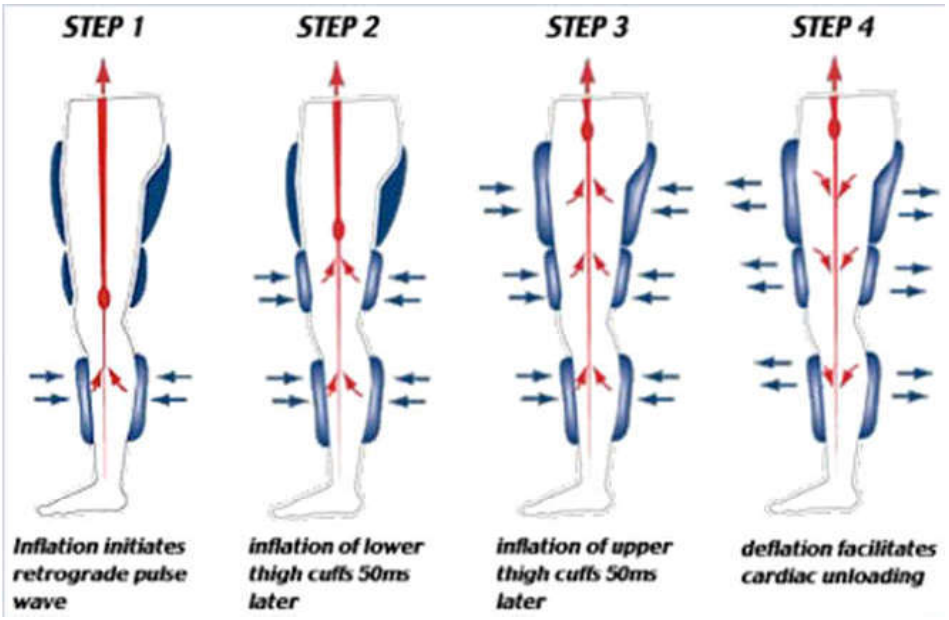

Fig. 1: Inflation and deflation of cuff during EECP procedure

How Does EECP Work

EECP causes immediate and sustained increase in the heart's blood supply by:

- Dilating coronary blood vessels
- Opening dormant collaterals
- Creating new blood vessels (angiogenesis)

ECPP treatment helps form a network of tiny blood vessels that make it possible for blood to detour around blocked or narrowed arteries. This is referred to as "collateral circulation". Collateral circulation is actually a natural phenomenon that can be developed with cardiovascular exercise also. However, the natural development of collateral circulation is a gradual process that takes years. EECP treatment triggers and accelerates this collateral circulation and makes it permanent. In fact, it is found that 35 sessions of EECP have the same effect as athletic training for 5 years.

A prospective interventional study of 50 patients by Eslamian et al demonstrated significant difference between perfusion scan ischemia severity before and 1-month post-EECP completion (P=0.04). A prospective study by Buschmann et al showed significant improvement in coronary flow index (from 0.08±0.01 to 0.15±0.02; P< 0.001) and fractional flow reserve (from 0.68±0.03 to 0.79±0.03; P= 0.001) in EECP-treated patients (n=16) compared to none in the control group (n=7), indicating the stimulation

of coronary arteriogenesis via EECP in patients with stable coronary artery disease.

EECP also tends to improve your endothelial cell function (the cells that line your coronary arteries), which determine your chance of getting heart attacks.EECP responders have significant immediate increase in the reactive hyperemia-peripheral arterial tonometry (a non-invasive method of measuring peripheral endothelial function) index after each treatment and at 1-month. 36 Endothelium plays an integral part in vascular homeostasis, and its dysfunction leads to imbalance between nitric oxide—a potent vasodilator, anti-proliferative, anti-inflammatory molecule—and endothelin-1—a potent vasoconstrictor, mitogen, and pro-inflammatory molecule [11-15].

Role of EECP in Angina

The multicenter study-EECP (MUST-EECP) was the landmark prospective, blinded, multicenter study that randomly assigned 139 patients with chronic stable angina and positive exercise stress tests to full-dose EECP or a sham method with minimal pressures. The study showed significant increase in exercise time post-EECP from baseline (426±20 to 470 ±20s, P<0.001) versus the sham group (432±22 to 464 ± 22s, P<0.03), and significant improved time to ≥ 1mm ST-segment depression in the EECP group (337±18 to 379±18s, P<0.002) compared with the sham group (326±21 to 330±20s, P<0.74). These results were maintained 12 months after EECP treatment.

The IEPR demonstrated that 78% of patients had a reduction of ≥ 1 angina class, and 38% of patients had improvement of at least two classes. At least a 50% reduction in frequency of angina was experienced by 76% of patients as well as improvement in quality-of-life assessment that was sustained for at least 2-years. Loh et al conducted a follow-up review in 2008 that followed 1061 patients from the IEPR-1 who maintained significant improvements in both weekly anginal events and quality of life at 3-years following completion of EECP therapy, compared with data obtained 1-week post-therapy.

A 5-year, single-center, non-randomized study in 33 patients with coronary artery disease, treated with EECP and grouped as responders vs non-responders found that major adverse cardiovascular events or mortality occured in 6 of 7 patients (86%) in the non-responder group and 6 of 26 patients (23%) in the responder group [12]. The overall 5-year survival of EECP-treated patients was 88%, comparable to that seen with medical and revascularization therapies. At 5-years of follow-up, 64% of patients were alive without interim cardiovascular events or need for revascularization.

Role of EECP in Congestive Heart Failure

Earlier studies have indicated a higher incidence of heart failure in patients with left ventricular dysfunction based on EECP increasing venous return and preload, hence precipitating pulmonary edema. The Prospective Evaluation of Enhanced External Counterpulsation in Congestive Heart failure (PEECH) 20 trial of 187 subjects with stable, symptomatic, mild-to-moderate heart failure (left ventricular ejection fraction [LVEF] ≤ 35 %) on optimal medical management demonstrated a significant increase in exercise time of at least 60 seconds in the EECP group (35%) compared to control group (25%), with a significant improvement of the Minnesota Living with Heart Failure score at 1 week and 3 months after treatment.

There was no significant difference in the peak VO2 between the groups. A subgroup analysis of patients over age 65 from the PEECH trial (EECP n=41, control n=44) demonstrated a 6-month higher response rate in the peak VO2 group compared to the control group (29.7% vs 11.4%, P=0.017). The PEECH trial further demonstrated that 33.3% of patients showed improvement of at least one class of New York Heart Association (NYHA) classification 1-week post-EECP therapy, with 31.3% of patients reporting improvement in classification 6-months post-therapy. Of note, 11.4% and 14.3% of placebo patients reported the same results, respectively.

Role of EECP in Hypertension

A study of 108 consecutive patients receiving EECP demonstrated a significant (6.4±16.2 mm Hg) reduction in systolic blood pressure at the end of therapy with no statistically significant effect on diastolic blood pressure or heart rate. Systolic blood pressure increased in the two lowest strata (<100 mmHg and 101–110 mmHg) and decreased in the remaining strata (111–120 mmHg, 121–130 mmHg, 131–140 mmHg, and ≥141 mmHg) (P< 0.001). These stratified differences were sustained after each EECP session as well as the immediate end and at 6 weeks of the EECP course.

A recent study by Gurovich and Braith demonstrated that even a single session of EECP-related blood flow patterns improved flow-mediated dilation in femoral and brachial arteries in healthy subjects.

EECP in Acute Coronary Syndrome with Cardiogenic Shock

A single-center, prospective study of ten patients with acute coronary syndrome and/or cardiogenic shock, ineligible for IABP counterpulsation, and received two to four 1-hour bedside treatments by portable EECP demonstrated a lack of portable EECP-related adverse effects like bleeding complications, heart failure exacerbation, skin breakdown, or interference with nursing care. EECP treatment resulted in significant increase in 30-minute mean arterial pressure compared to baseline (P=0.0002) and dyspnea severity (P=0.036) without significant changes in heart rate, pulse oximetry, or urine output. This study also suggests improved cardiovascular performance and possibly clinical outcomes with acute inpatient EECP in patients with acute coronary syndrome and cardiogenic shock [15-22].

What Are the Benefits of EECP Treatment?

- Increased oxygen supply for the heart
- Decrease in chest pain
- Improved EKG response to exercise
- Decrease in nitroglycerin use
- Increase in energy
- Increased exercise duration
- Decreased episodes of Angina
- Improvement in overall quality of life, mood and feeling of well-being

Advantages of EECP over Surgery

- Non-invasive therapy
- Carried out on out-patient basis – no need for hospitalization
- Low risks
- No additional medication required
- No recuperation times
- No side-effects
- No risks of surgery [23]

Comparison of EECP Treatment with other Interventional Treatments

Even though the patients treated with ECPP are sicker group when compare to the patient undergone interventional procedures the results are comparable in spite of the disparity of risk profile in the two groups. The 5-year survivals of ECP patients are 88% similar to the results seen in contemporary Bypass and angioplasty trail. A Study comparing two ECPP registries at Pittsburgh and Angioplasty registry at National heart lung and Blood institute shows the 1-year survival and adverse events results are comparable. But 17.2% of angioplasty patients went for repeat angioplasty procedure while only 6.3% of ECPP patients underwent repeats ECPP. Also, twice the no of patients in Angioplasty group reported to use Short time nitroglycerin when compare to ECP group [24].

How much does it Cost to a Patient?

The treatment cost for 35 days is currently between Rs 85,000 and Rs 1,00,000. Initially, the treatment was provided only in cardiology super specialty hospitals but now due to the growing acceptance of the treatment, it is now offered in smaller hospitals and physician's office. As the treatment is moving from major urban cities to rural areas there will be considerable cost reduction as the operational cost can be brought down due to the positioning of EECP as a standalone treatment Centre. Moreover, as the treatment is out-patient, there will not be additional cost factor involved as in other in-patient treatments and hospitals have also started charging the treatment on multiple instalments basis rather than upfront full payment to reduce the cost burden on the patients [25].

Conclusion

EECP has been used in the treatment of angina for the past two decades with a record of safety and, more recently, several publications which support its efficacy. It is approved by the FDA for the treatment of chronic or unstable angina and in patients with congestive heart failure. Treatment has been associated with improved exercise tolerance and myocardial perfusion, as evidenced by nuclear imaging and positron emission tomography. More research will hopefully shed additional light on the mechanism of action and verify the long-term attenuation of symptoms in patients with unstable angina pectoris and in those with congestive heart failure.

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