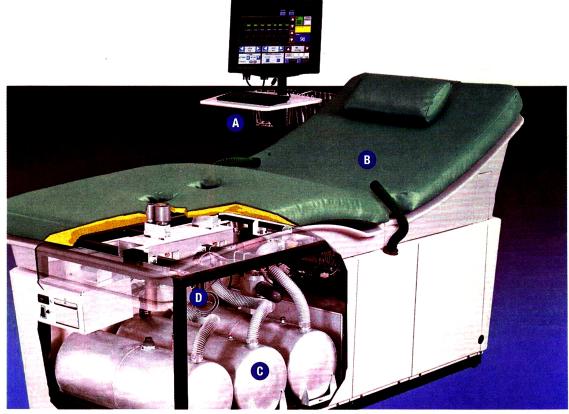


EECP for refractory angina, heart failure

The technique of counterpulsation, studied for almost one-half century now, is considered a safe, highly beneficial, low-cost, non-invasive treatment for angina and heart failure patients



■A) Integrated Work Surface B) Comfortcurve™ Treatment Mattress C) Trinity™ Pneumatic Delivery System D) Welded Steel Frame Construction



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Between 25,000 and 75,000 new cases of angina refractory to maximal medical therapy and standard coronary revascularisation procedures are diagnosed each year. Heart failure has plased an enormous burden on the healthcare system.

In recent years, improvements in both pharmacologic and revascularisation therapies have greatly increased life expectancy for patients with coronary artery disease (CAD). As patients with more extensive CAD live longer, many develop myocardial ischemia and clinical angina that is not amenable to traditional revascularisation therapy. Patients with severe, symptomatic, chronic CAD have been described as having refractory angina;

they have also been termed 'no-option' patients. Enhanced external counterpulsation (EECP) is an emerging option in this unique and growing group of patients.

EECP

The technique of counterpulsation, studied for almost one-half century now, is considered a safe, highly beneficial, low-cost, non-invasive treatment for these angina and heart failure patients. A standard EECP treatment comprises 35 hours over seven weeks. Cuffs wrapped around the lower extremities and the hips are inflated with air in each diastole and deflated instantly at onset of systole.

EECP has a long lasting effect on angina



pectoris. Several studies using different methods of assessment with objective blinded methods, have shown that EECP-therapy reduces the ischemic area of the left ventricle. EECP has been proven to provide symptomatic benefit in angina patients, but has not been proven to show an increase in life expectancy or decrease in cardiovascular events. EECP in heart failure has been proven to be safe, but its efficacy is still uncertain. Recent evidence suggests that enhanced external counterpulsation (EECP) therapy may improve symptoms and decrease long-term morbidity via more than one mechanism, including...

- ♦ Improvement in endothelial function, reduction of inflammatory cytokines, Enhanced external counterpulsation (EECP), increases endothelial shear stress, on circulating levels of inflammatory biomarkers and adhesion molecules in patients with angina pectoris.
- Promotion of collateralisation, enhancement of ventricular function.
- ♦ Improvement in oxygen consumption (VO2).
- ♦ Regression of atherosclerosis.
- ♦ Peripheral training effects similar to exercise.

EECP treatment reduces arterial stiffness and improves wave reflection characteristics in patients with refractory angina. These changes decrease LV afterload and myocardial oxygen demand and reduce the number of angina episodes, therefore enabling patients to participate in continuous exercise programs which in turn may provide long-term benefits and sustained improved quality of life.

Numerous clinical trials in the last two decades have shown EECP therapy to be safe and effective for patients with refractory angina with a clinical response rate averaging 70-80 per cent, which is sustained up to five years. It is not only safe in patients with coexisting heart failure, but also is shown to improve quality of life and exercise capacity and to improve left ventricular function long-term. Interestingly, EECP therapy has been studied for various potential uses other than heart disease, such as restless leg syndrome, sudden deafness, hepatorenal syndrome, erectile dysfunction, etc.

Efficacy and safety of EECP

A retrospective analysis was conducted of 79 consecutive patients who underwent enhanced external counterpulsation (EECP) at West Virginia University Hospitals during the period of November 1998 to September 2005 to determine its efficacy and safety in treating angina. A chart review and/or phone survey was performed to analyse pertinent clinical data (sublingual nitroglycerin use and

angina class) pre and post EECP. A total of 60 (76 per cent) patients who were referred for EECP successfully finished the 35 treatments. Seventy-five per cent of the patient population improved at least one angina class after a full course of treatment. Therapy was discontinued due to adverse effects in 12 (15 per cent) patients. Statistically significant improvements in angina class and reduction in anti-angina medications were observed in every comorbid subgroup analysed, including patients with peripheral vascular disease, diabetes, hyperlipidemia, hypertension, smoking, Post-MI, and LVEF < 40 per cent (P < .05, Wilcoxon Signed-Rank test). Overall, EECP was effective in improving angina as reflected in a substantial reduction in antiangina medications in 59 (75 per cent) patients.

In a study by Yavari M et al, 77 per cent of patients who had undergone EECP had a positive clinical response. Exercise test duration and CCS functional class improved after the treatment. However, EECP had no significant effect on echocardiographic parameters. Efficacy was independent of age, gender, CAD risk factors, prior CCS functional class and echocardiographic parameters. Patients without left main artery involvement and those who had at least one non-obstructed artery demonstrated a greater likelihood of improvement. The results of this study suggested that EECP is a safe, well tolerated, and significantly effective treatment for angina pectoris.

In a study to evaluate the immediate response, durability and clinical events over a two-year period after EECP treatment in 112 patients with Canadian Cardiovascular Society (CCS) class II angina versus 1,346 patients with class III-IV angina using data from the International EECP Patient Registry (IEPR,







treatment with EECP significantly (by at least one CCS class) reduced angina frequency, nitroglycerin use, and improved quality of life in both groups. At two-year follow-up, 74 per cent of class II and 70 per cent of class III-IV patients remained free of major adverse cardiovascular events (MACE) and continued to demonstrate a durable CCS class improvement over baseline. The robust effectiveness of EECP as a noninvasive device, together with its relatively low start-up and recurrent costs, makes it an attractive consideration for treating patients with milder refractory angina in addition to the patient with severely disabling angina treated in current practice.

The long-term outcome of EECP treatment at a Scandinavian centre, in relieving angina in patients with chronic refractory angina pectoris showed that EECP is a safe treatment for highly symptomatic patients with refractory angina. The beneficial effects were sustained during a 12-months follow-up period.

Other applications of EECP in clinical practice

Critically ill patients of acute coronary syndrome and/ or cardiogenic shock: EECP is safe and feasible for acute bedside therapy of critically ill patients with acute coronary syndrome and/or cardiogenic shock who are not candidates for IABP.

LV dysfunction: Enhanced external counterpulsation (EECP) therapy has emerged as a treatment option for patients with angina and LV dysfunction and has been shown to improve clinical outcomes and LV function. In a prospective cohort study which

included 450 patients with LV dysfunction (ejection fraction <or=40 per cent) treated with EECP therapy for refractory angina, clinical outcomes, number of all-cause ED visits, and hospitalisations within the six months before EECP therapy were compared with those at six-month follow-up. Despite the unfavorable risk profile, refractory angina patients with LV dysfunction achieved a substantial reduction in all-cause ED visits and hospitalisation rates at sixmonth follow-up. EECP therapy appears to offer an effective adjunctive treatment option for this group of patients.

Syndrome X: Enhanced external counterpulsation (EECP) was used to treat 30 patients with refractory angina due to cardiac Syndrome X, with an initial improvement in CCS angina class (3.57 to 1.43; p<0.001) and regional ischemia in all treated patients. At a mean of 11.9 months follow-up, 87 per cent of patients had sustained improvement in angina and were without major adverse cardiovascular events. EECP, by improving endothelial function, may be an effective and durable treatment for this often difficult to treat problem.

Medically refractory angina patients with erectile dysfunction: Patients with refractory angina often suffer from erectile dysfunction. Enhanced external counterpulsation (EECP) decreases symptoms of angina, and increases nitric oxide release. A cohort of 120 men (mean age 65.0+/-9.7) with severe coronary disease with 69 per cent having a prior myocardial infarction, 90 per cent prior coronary artery bypass graft or percutaneous coronary intervention, 49 per cent with three vessel coronary artery disease, 86 per cent were not candidates for further revascularisation, 71 per cent hypertensive, 83 per cent dyslipidaemia, 42 per cent diabetes mellitus, 75 per cent smoking and 68 per cent using nitrates. Functional status was low with a mean Duke Activity Status Inventory score of 16.6+/-14.8. After 35 h of EECP anginal status improved in 89 per cent, and functional status in 63 per cent. A comparison of the IIEF scores pre- and post-EECP therapy demonstrated a significant improvement in erectile function from 10.0+/-1.0 to 11.8+/-1.0 (p=0.003), intercourse satisfaction (4.2+/-0.5) to 5.0+/-0.5, p=0.009) and overall satisfaction (4.7+/-0.3 to 5.3+/-0.3, p=0.001).

However, there were no significant changes in orgasmic function (4.2+/-0.4 to 4.6+/-0.4, p=0.19) or sexual desire (5.3+/-0.2 to 5.5+/-0.2). The findings suggest that EECP therapy is associated with improvement in erectile function in men with refractory angina.

EECP has a long lasting effect on angina pectoris. Several studies using different methods of assessment with objective blinded methods, have shown that EECP-therapy reduces the ischemic area of the left ventricle