Original Research Article

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Evaluation of the role of enhanced external counter pulsation in patients with chronic heart failure

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ABSTRACT

Background: The incidence of Chronic Heart failure (CHF) has reached epidemic proportions in developing countries. The prevalence also increases as the patient population ages. Heart failure accounts for between 5% and 10% of all hospital admissions and is the most frequent cause of hospitalization in the elderly. The aim of this single centre observational study was to find out the efficacy of EECP in improving functional capacity and LV function in symptomatic chronic heart failure patients with mild to moderate LV dysfunction irrespective of their etiology.

Methods: Thirty-six symptomatic patients in NYHA class II and III were included in this study. All the patients underwent one hour EECP therapy for thirty-five sessions over a period of seven weeks. NYHA classification, sixminute walk test, two dimensional and Tissue Doppler Echocardiographic examination were done before and after EECP therapy.

Results: At the end of EECP therapy there was improvement in functional class. Eleven out of thirty-six patients were asymptomatic. The mean distance covered in six-minute walk test was also significantly increased after the therapy. The Echocardiographic parameters like Ejection Fraction (EF), Systolic excursion of mitral valve annulus (S'), Ratio between mitral flow E Velocity & Mitral annular E velocity (E/E') significantly improved after EECP.

Conclusions: In this study, it was concluded that there was significant improvement in symptoms, functional capacity and LV function in Chronic Heart Failure patients after EECP therapy.

Keywords: CHF, EECP, SWT, EF, E/E', NYHA, PVO2, S', 6MWT

INTRODUCTION

The incidence of Chronic Heart failure (CHF) has reached epidemic proportions in developing countries. The prevalence also increases as the patient population ages. Heart failure accounts for between 5% and 10% of all hospital admissions and is the most frequent cause of hospitalization in the elderly. Heart failure is also associated with significant morbidity and mortality, contributing large economic burden.

The pathophysiology of heart failure is a continuous process rather than a series of individual events which

lead to the realization that early identification and treatment of the disease can significantly reduce morbidity, mortality and costs.

In patients with CHF, functional capacity is a method to evaluate patient's ability to perform daily activity and to plan therapeutic strategies for the treatment, thus to slow or reverse cardiac remodeling, prolonging the patient's life, as well as to improve the patient's overall quality of life.

Assessment of functional capacity has traditionally been done by merely asking patients questions related to their symptoms. However, patients vary in their recollection and may report overestimations or underestimations of their true functional capacity. Evaluation of functional status by NYHA classification is limited by a high degree of subjectivity. Hence objective measurements are usually better than self-reports.

In the early 1960s, Balke developed a simple test to evaluate the functional capacity by measuring the distance walked during a defined period of time. A 12-minute field performance test was then developed to evaluate the level of physical fitness of healthy individuals. The walking test was also adapted to assess disability in patients with chronic bronchitis. In an attempt to accommodate patients with respiratory disease for whom walking 12 minutes was too exhausting, a 6-minute walk was found to perform as well as the 12-minute walk. A recent review of functional walking tests concluded that the 6-minute walk test (6MWT) is easy to administer, better tolerated, and more reflective of activities of daily living than the other walk tests.

Though the gold standard for the evaluation of functional capacity in CHF is peak O_2 consumption at cardiopulmonary exercise test (CPET), is time consuming, requiring relatively expensive instruments and an experienced team. Hence CPET may be performed in less than 5% of the patients with CHF. Six-minute walk test (6MWT) has been proposed as a simple, inexpensive, reproducible alternative to CPET.

Six-minute walk test

The 6MWT should be performed indoors, along a long, flat, straight, enclosed corridor with a hard surface. The walking course must be 30 m in length, 100-ft hallway is, therefore, required. The length of the corridor should be marked every 3 m. The turnaround points should be marked with a cone any bright object. A starting line, which marks the beginning and end of each 60-m lap, should be marked on the floor. The use of a treadmill for 6-minute walk testing is not recommended.

The required Equipment were Countdown timer or stopwatch, wheel chair, worksheets on a clipboard, source of oxygen, Sphygmomanometer, Defibrillator and Cardiverter. Patient should wear comfortable clothing and appropriate shoes for walking. The patient's usual medical regimen should be continued.

A light meal is acceptable before the test. A warm-up period before the test should not be performed. The patient should sit at rest in a chair, located near the starting position, for at least 10 minutes before the test starts. During this time, check for contraindications, measure pulse and blood pressure and pulse oximetry (optional). A proper Instruction about the test and the timing should be given to the patient before the test. Patient advised not talk to anyone during the walk and standard phrases of encouragement is recommended.

Patient should be informed 15 seconds before completion of test. Examiner should record and calculate the total distance walked.¹

The 6MWT reproduces the activity of daily life and this is particularly relevant in elderly patients who usually develop symptoms below their theoretical maximal exercise capacity. Despite some limits 6MWT is attractive for patients with CHF allowing an objective evaluation of exercise tolerance, a better prognostic evaluation and a guide to evaluate response either pharmacological or non-pharmacological treatment and also showed a good reproducibility. In healthy subjects, the 6-min walk distance (6MWD) ranges from 400 to 700 m, the main predictor variables being gender, age and height.²⁻⁴

EECP

A significant proportion off patients with heart disease are not amenable to standard revascularization procedures, such as angioplasty and CABG, because of unsuitable coronary anatomy, multiple previous revascularization attempts, age, additional co-morbid conditions, or patient preference. Such patients require physicians to seek other treatment options.

New treatment modalities, which are at various stages of clinical evaluation, include minimally invasive bypass surgery, spinal cord stimulation, transcutaneous electrical nerve stimulation, trans-myocardial laser revascularization, stem cell therapy, and EECP. Of these modalities, EECP is the only truly non-invasive, atraumatic technique for which clinical anti-ischemic improvements have been shown.

EECP is a registered trademark of Vasomedical, Inc., Westbury, New York, which manufactures EECP equipment in the United States. Most published studies have used Vasomedical EECP equipment (Figure 1). EECP therapy consists of three sets of pneumatic cuffs attached to each of the patient's legs to the calf and lower and upper thigh. The inflation of the cuffs is triggered by a computer, and timing of the inflation is based on the R wave of the electrocardiogram.

The EECP therapist adjusts the inflation and deflation timing to provide optimal blood movement per a finger plethysmogram waveform reading.

This produces a retrograde flow of blood in the aorta (aortic counter pulsation), resulting in a diastolic augmentation of blood flow and also an increase in venous return, which leads to an improved coronary perfusion pressure during diastole. Shortly afterwards, the cuffs deflate before the onset of systole, thereby decreasing vascular resistance, assisting with systolic unloading and decreasing cardiac workload.



Figure 1: EECP in GVMCH Vellore.

The often-postulated mechanism of action of EECP describes increase in diastolic pressure augmentation during the rapid cuff inflation, analogous to IABP counter-pulsation.

Indeed, acute coronary artery flow, determined by both Doppler and angiographic techniques, is increased during EECP suggesting that external compression may serve as a potential mechanical assist device remains unclear how diastolic augmentation could translate into the chronic anti-ischemic benefits of EECP (Figure 2).

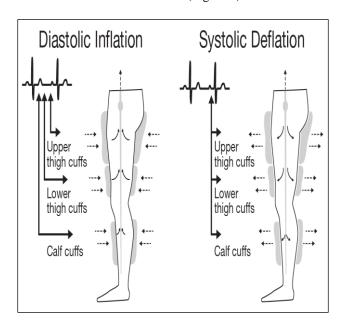


Figure 2: Methodology in EECP.

It is conceivable that diastolic augmentation and possible increased coronary shear forces could stimulate arteriogenesis, the maturation of epicardial vessels or opening of dormant collaterals, and/or angiogenesis, the formation of new vessels that perfuse the myocardium.

The beneficial effects include reduced myocardial oxygen demand, increased venous return and cardiac output, improved endothelial function, prolonged time to exercise-induced ST depression on electrocardiogram,

and improvement or resolution of myocardial perfusion defects (Figure 3).

Overall, EECP has been proven to be a safe therapy, as reported by the International EECP patient registry (IEPR) in 2000.

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.

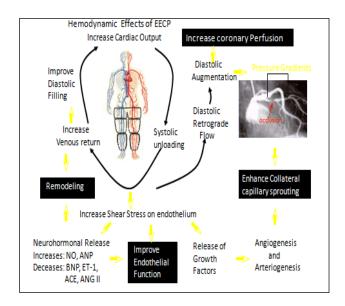


Figure 3: Postulated mechanisms of action.

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. The typical EECP course involves 35 one-hour sessions that the patient attends each week.

In this observational study, we are taking NYHA class six-minute walk test Echocardiographic examination to assess the influence of EECP in improving LV function in chronic heart failure patients.

METHODS

This study was conducted in Department of Cardiology, Government Vellore Medical College and Hospital, Vellore, Tamil Nadu. 36 patients who underwent EECP therapy during the period February 2016-17 were selected for this study.

Among these patients 23 were males and 13 were females. Risk factors like hypertension, diabetes mellitus, dyslipidemia and smoking were taken and patients were stratified accordingly.

Following criteria were applied for patient's selection:

Inclusion criteria

- Age: 25 years to 85 years
- Target lesion inaccessible for PCI/CABG
- High risk for PCI/CABG
- Patient refusal to PCI/CABG
- Symptomatic even after PCI/CABG
- Patients preference
- NYHA class II-III.
- LV Dysfunction- EF 25-45%.

Exclusion criteria

- Angina class- IV
- Dyspnoea- NYHA class-IV
- Acute myocardial infarction
- Unstable angina
- Tachy and brady arrhythmias.
- Severe hypertension >180/100 mmHg.
- Peripheral vascular disease
- Severe co-morbid conditions

For all the patients included in the study a detailed clinical history was taken with grading according to the NYHA classification.

Pulse, blood pressure, ECG were recorded in all the patients.

Echocardiography examinations with following measurements were made:

- Ejection fraction (EF)
- Mitral velocity deceleration time (DT)
- Systolic excursion of mitral valve annulus (S')
- Ratio between mitral flow E velocity and mitral annular E velocity (E/E').

All the patients underwent 35 sessions of EECP over a period of seven weeks. After completion of the EECP schedule all the above parameters were repeated

RESULTS

The end results were analyzed statically (Table 1-3) which showed:

Stastical analysis

Hypothesis

Null hypothesis h0: There is no significance difference between the means.

Alternate hypothesis h1: there is a significance difference between the means.

Table 1: Statistical analysis summary.

Variables	Pre EECF	Pre EECP			Post EECP		
	Mean	N	STD±	Mean	N	STD±	
Systolic BP (mmHg)	116	36	14.3	116	36	9.6	
Diastolic BP (mmHg)	75	36	9.6	74	36	11.5	
Pulse	75	36	8.7	82.6	36	6.7	
Six-minute walk test (meters)	373	36	79.2	466	36	80.06	
EF (%)	34.14	36	4.9	41.58	36	5.123	
S' cm.sq.	9	36	1.3	6.9	36	1.6	
E/E'	13.9	36	2.1	8.4	36	2.4	
DT (milli sec)	220	36	37.2	402	36	36.9	

There was significant functional improvement in the symptom which was evidenced by conversion from NYHA Class II and III to NYHA Class I.

Significant Post EECP improvement in the pulse Rate, ejection Fraction, (Figure 5), increase in the distance of six-minute walk test (Figure 6), and the ratio between

Mitral flow E velocity to Mitral annulus E velocity i.e. E/E' (Figure 7)) and systolic excursion velocity of mitral annulus i.e. S'.

There was no significant Post EECP change in the Blood pressure and Mitral velocity deceleration time.

Table 2: Statistical analysis of paired samples.

Paired samples statistics						
		Mean	N	Std. Deviation	Std. Error Mean	
Pair 1	Pre-BP systole	118.06	36	14.307	2.384	
	Post-BP systole	116.39	36	9.607	1.601	
Pair 2	Pre-BP diastole	75.72	36	7.741	1.290	
raii 2	Post BP diastole	74.17	36	11.052	1.842	
Pair 3	Pre-pulse	75.06	36	8.770	1.462	
Pair 3	Post-pulse	82.61	36	6.741	1.124	
Pair 4	Pre-six	373.25	36	79.205	13.201	
Pair 4	Post-six	466.81	36	80.064	13.344	
Pair5	Pre-EF	34.14	36	4.906	0.818	
Pairs	Post-EF	41.58	36	5.123	0.854	
Pair 6	Pre-S	3.97	36	1.362	0.227	
Pair 0	Post-S	6.92	36	1.663	0.277	
Pair 7	Pre-EE	13.97	36	2.118	0.353	
Pair /	Post-EE	8.47	36	2.478	0.413	
Pair 8	Pre-DT	220.06	36	37.265	6.211	
raii 8	Post-DT	402.83	36	1336.917	222.820	

Table 3: Statistical analysis of paired samples correlations.

Paired samples correlations								
Pa	ir	N	Correlation	Sig.	Remark			
1	Pre-BP high and Post BPH	36	0.197	0.250	Not significant			
2	Pre-BP low and Post BPL	36	0.101	0.559	Not significant			
3	Pre-pulse and Post pulse	36	-0.425	0.010	Significant			
5	Pre-six and Post six	36	0.659	0.000	Significant			
6	Pre-EF and Post EF	36	0.753	0.000	Significant			
7	Pre-S' and Post S'	36	0.491	0.002	Significant			
8	Pre-E/E' and Post E/E'	36	-0.046	0.788	Not significant			
9	Pre-DT and Post DT	36	0.104	0.545	Not significant			

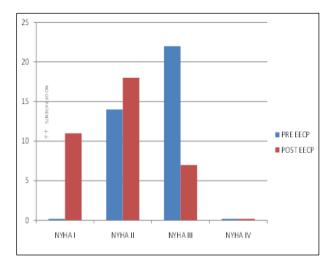


Figure 4: NYHA and EECP.

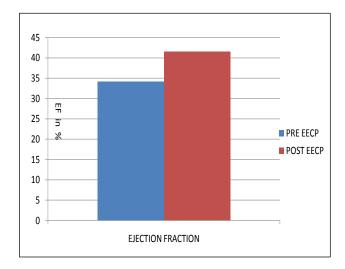


Figure 5: Ejection fraction and EECP.

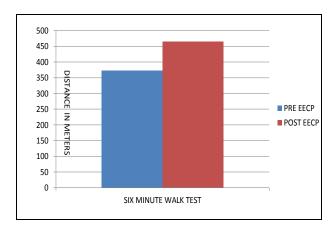


Figure 6: Six-minute walk test and EECP.

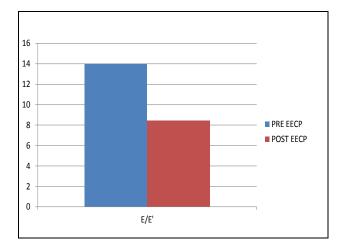


Figure 7: Mitral flow velocity -mitral annular velocity ratio in EECP E/E'.

DISCUSSION

Attempts to measure functional capacity in persons with chronic heart failure have varied from questionnaires, grouping into NYHA classes, peak VO2 measurement, and submaximal exercise testing. The 6MWT is a low cost, simple test that requires little equipment and shows good to excellent test-retest reliability across the literature.^{5,6}

Guyatt, in a very early study clarified the usefulness of available measures like questionnaires, 6MWT, and bicycle exercise test in assessing functional status and exercise capacity of patients with lung disease and CHF.

The correlation of the 6MWT with the questionnaires and with cycle ergo meter indicates that the 6MWT was considered superior to the Questionnaires in that it was objective and reproducible. The 6MWT appears to measure the patient's ability to undertake physically demanding activities of daily living and a useful tool to measure cardio respiratory response after intervention.⁷

Riley and investigators assessed the reproducibility of the 6MWT and its validity as a measure of functional

capacity in patients with CHF. They measured VO₂ not only during a treadmill exercise test, but also during performance of the 6MWT and found that 6MWT had good reproducibility and good correlation with treadmill-measured peak VO₂.

The VO₂ measured during the 6MWT was less than the exercise treadmill test peak VO₂ for all patients, which provides support for the belief that the 6MWT is a submaximal exercise test. Therefore, they concluded that 6MWT provides for less variability and a more accurate assessment of functional capacity, good correlation with peak VO₂, but is likely a better measure of sub maximal exercise.⁸

Roul in his study evaluated the potential of the 6MWT and it was compared with peak VO_2 in predicting outcome of patients with NYHA class II or III heart failure. When using a threshold of 300 m the sensitivity of the 6MWT was 89%, specificity 60%, and positive predictive value 80%. There was a moderate correlation between distance walked and peak VO2 when a distance of 300 m was used as a threshold.

Peeters in a prospective trial, patients with CHF, NYHA classes II and III were compared with healthy, untrained controls. All the participants underwent a 6MWT and a symptom-limited treadmill test and found a significant lower symptomatic VO2 max occurred in NYHA class III than in NYHA class II. The authors concluded that the 6MWT was correlated with treadmill distance, well tolerated by the elderly, and provided functional differentiation between NYHA classes II and III. 10

Lipkin in a study assessed the exercise capacity of patients with NYHA class II-III and normal subjects by determining the oxygen consumption attained during a maximal exercise test and by measuring the distanced walked during the 6MWT. There were significant differences in maximal oxygen consumption and distance walked between normal subjects, patients with class II heart failure and class III heart failure (p<0.001).

The findings of the study also indicated that the patients preferred the 6MWT to the treadmill, finding it easier and more closely related to their daily physical activity. Some may have been poor performers on the treadmill test and did better during the 6MWT. The authors conclude that in patients with CHF the 6MWT provides an objective assessment of exercise capacity that could usefully supplement clinical information obtained from the history and physical examination. ¹¹

There were some studies did not find a significant correlation between 6MWD and VO_2 max from exercise testing. Lucas investigated whether the 6MWT distance was related to peak VO_2 for individuals with advanced heart failure. He opined 6MWT distance was not well correlated with peak VO_2 and therefore considered not valid to predict peak VO_2 for patients with advanced

heart failure. Green and colleagues suggested that the Shuttle Walk Test (SWT) is a more predictive measure of peak VO_2 than 6MWT, thus is a more valid measure of functional capacity than the 6MWT in patients with CHF.

Morales, concluded that the 6MWT appears inferior to the SWT with respect to predicting functional capacity as defined as peak VO_2 , although still considered to have good reproducibility, moderate correlation with peak VO_2 levels, and is 83% accurate in predicting peak VO_2 (<14mL/kg/min) as long as distance walked is greater than 450 meters. 12,13

As EECP has been more seriously considered as a viable treatment for reduction of symptoms in patients with refractory stable angina, the feasibility of using it in other populations has been considered. Initial studies using EECP demonstrated safety in congestive heart failure from the theoretical risk of acutely increasing preload and precipitating pulmonary oedema. However, assessment of major adverse event rates demonstrated that most events were related to underlying illness rather than to treatment.

Some preliminary studies observed the effects of EECP on ventricular function rather than on angina and demonstrated improved Canadian Functional Class, Minnesota score of quality of life, peak oxygen consumption, and treadmill time following EECP; these improvements were maintained at 6 months and EECP was determined to be safe and effective in the treatment of heart failure. 13,14

Other studies comparing echocardiography in a small number of patients with class II–III heart failure demonstrated improvement in ejection fraction and preload adjusted maximal power following EECP, a measure of the maximal hydraulic power generated by the left ventricle. ^{15,16}

In addition to using EECP in treating heart failure, utility in the management of angina in patients with ventricular dysfunction has been evaluated. In all, 312 patients from the IEPR with moderately reduced LV ejection fraction were compared with those with preserved LV systolic function post EECP and after 6 months. Immediately following EECP, both groups showed considerable improvement.

However, there were more patients in the group without LV systolic dysfunction who improved by at least one CCS angina class (76.2 vs. 67.8%). A similar percentage of patients in each group discontinued sublingual nitroglycerine. There was a higher rate of major events in the follow-up period including congestive heart failure exacerbation (9.9 vs. 3.7%), death (9.3 vs. 2.2%), and composite outcome of death, myocardial infarction, CABG, and PCI (15.4 vs. 8.3%) in patients with LV systolic dysfunction. There was no significant difference in the percentage of patients who maintained improvement in angina at 6 months.

Thus, patients with LV systolic dysfunction did demonstrate an improvement, although not as substantial as patients with preserved systolic function, and improvement was maintained in both groups at 6 months.¹⁷

The Prospective Evaluation of Enhanced External Counter-pulsation in Congestive Heart-failure (PEECH) trial of 187 subjects with stable, symptomatic, mild-to-moderate heart failure [left ventricular ejection fraction (LVEF) \leq 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 demonstrated a 6-month higher response rate in the peak VO₂ group compared to the control group. ^{18,19}

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 Improvements in quality-of-life assessments without any major complications have also been demonstrated at 1 week and 6 months after EECP.

In a study of 450 patients with refractory angina and left ventricular dysfunction [ejection fraction (EF) $<30\pm8\%$] EECP significantly reduced 6-month emergency room visits by 78% and hospitalizations by 73 %.²⁰

Significant improvements in B-type natriuretic peptide, uric acid, freeT3/free-T4 ratio, and mitral annular E velocity have been observed in a prospective cohort study post-EECP therapy compared to baseline.²²

EECP therapy has been shown to significantly increase LVEF and significantly reduce resting heart rate. EECP therapy has also been shown to be of benefit for patients with ischemic and non-ischemic cardiomyopathy, systolic or diastolic dysfunction.

A study of 26 patients with heart failure (Class II/III NYHA and average EF of 23%) showed clinical benefit without any major adverse cardiac effect. ^{23,24}

CONCLUSION

In this observational study, we found that the symptomatic chronic Heart Failure patients with mild to moderate LV dysfunction showed significant improvement post EECP therapy both in terms of clinical and echo-cardiographic parameters.

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Ethical approval: The study was approved by the

institutional ethics committee

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