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## Original Article

## Can enhanced external counter pulsation as a non-invasive modality be useful in patients with ischemic cardiomyopathy after coronary artery bypass grafting?

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## ABSTRACT

**Background:** Angina symptom in patients with ischemic cardiomyopathy (ICM) after coronary artery bypass grafting (CABG) surgery is a major challenging problem in practice. The choice among different treatment modalities available can be judged by different parameters especially measuring the risk/cost ratio to achieve the benefit. Enhanced external counter pulsation (EECP) is one of safest noninvasive modality for treatment of angina as well as it has an anti-failure effect.

**Patients and method:** 42 patients with ICM after CABG were suffering from stable angina and were treated at Al-Hayat Cardiology Centre in Tanta City (ACC). 20 patients of them (group A) received 35 sessions of EECP plus their anti-ischemic and anti-failure treatment, while the other 22 patients (group B) received only medical treatment and were followed up for 3 months regarding their angina class, functional class, frequency of angina attack, frequency of sublingual nitrate and rate of rehospitalization when needed during follow up period.

**Results:** Despite both groups had nearly similar severity of symptoms regarding the CCS class and NYHA class, yet patients in group A experienced significant improvement in comparison to patients in group B (p-value = .005, p-value = .002 respectively), and this was reflected on frequency of angina and need for sublingual nitrates per week which showed significant decrease in group A (p-value = .001).

**Conclusion:** As a non-invasive treatment modality EECP is very effective in improving the symptoms of angina and heart failure when combined with medical treatment in patients with ICM after CABG.

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## 1. Introduction

The negative impact of angina and heart failure symptoms after CABG on patient's quality of life is a well-known problem.<sup>1</sup>

The re-intervention by per cutaneous intervention (PCI) or redo CABG is not without high perioperative risk to treat such patients and sometimes such intervention is not feasible.<sup>2</sup>

Transmyocardial laser revascularization, Angiogenic therapy through the intracoronary or intramyocardial administration of growth factors or through gene therapy, or spinal cord stimulation all are different modalities have been studied in clinical trials to assess their efficacy in treating refractory angina.<sup>3–5</sup>

Prior studies have demonstrated the effectiveness of EECP in treating the refractory angina and improving the CCS class to the patients.<sup>6</sup>

Our objective in this study is see how much effective is the EECP as a non-invasive modality in improving angina and functional class in patients with ischemic cardiomyopathy after CABG in comparison to medical treatment only.

## 2. Patients and methods

From January 2015 to January 2017, a prospective, controlled and randomized study was carried out at Al-Hayat cardiology Centre (ACC); a private medical Centre specialized in cardiac patients care and registered at Ministry of health in Tanta city, Arab Republic of Egypt.

42 patients with angina and poor functional class due to ICM after CABG had their medical consultation and treatment at the Centre.

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Patients included in this study ( $n = 42$ ) were allocated into two groups, group A ( $n = 20$ ) included patients who received 35 sessions of EECP (Patients are treated for a one-hour daily program for a total of 35 sessions over 7 weeks according to recommendation of European Society of Cardiology) plus their medical treatment, and group B ( $n = 22$ ) included patients who received medical treatment only.

Direct consultation with the patients at the Centre was used to assess angina and heart failure classification. The Canadian Cardiovascular Society Functional (CCS) Classification was used to stratify the degree of angina. Heart failure status was assessed using the New York Heart Association (NYHA) Functional Classification. All of them were classified in NYHA class III or IV, their left ventricular function were impaired (ischemic cardiomyopathy) i.e. which is defined as the presence of left ventricular dilatation and systolic dysfunction with ejection fraction less than 45%.<sup>7</sup> LV EF for patients in group A was  $40.85 \pm 5.29\%$ , and in group B was  $43.00 \pm 6.05\%$ .

All patients included in this study had a clear data of having complete revascularization during their CABG surgery, under full and optimal anti angina and anti-failure medical therapy. ECG study was done daily before each session.

All patients must have echocardiographic study and whole arterial and venous duplex for lower limbs and carotid arteries as well as the abdominal aorta using (MySono U6 Samsung Medison machine) equipped with a multi frequency 2.5–4.0 MHz phased array transducer, the Duplex examination was performed using Linear transducer 5–10 MHz.

The ejection fraction “EF%” was calculated using biplane Simpson method. Diastolic dysfunction was assessed by tissue Doppler imaging which was used to measure mitral annular velocities. The peak systolic “S”, early diastolic “E”, atrial diastole “A” velocities were measured at both the mitral septal and lateral annulus, and the mean was taken E/E (Ratio between mitral flow E Velocity & Mitral annular E velocity). However, we did not take the diastolic dysfunction as a point of research in this study.

We excluded any patient with arterial aneurysms, deep vein thrombosis, severe aortic regurgitation which considered a contraindication for EECP and their INR should not exceed 1.5 if patients on warfarin.

Having a coronary angiographic study to determine the exact coronary lesion at the time of medical consultation was discussed with all patients, but patients included in this study preferred to try a non-invasive protocol of management either patients in group A or group B. Those who decided to have angiographic study and treated invasively were excluded.

The study was approved by the Human Ethics Committee and patient consent was waived.

### 2.1. The mechanism of action of EECP machine

The EECP machine used at ACC is the one manufactured by PSK Company (Chongqing PSK-Health Sci-tech Development Co., Ltd).

Our EECP machine model is (T1- touch screen); it consists of a treatment table, an air compressor, a console, two sets of three cuffs and pulse oximetry. Patient’s calves, lower thighs and upper thighs are wrapped in 3 compressive pneumatic cuffs during the EECP session.

It works like the intra-aortic balloon regarding the mechanism of action which is based on trigger induced by electrocardiogram (ECG), where the sequential compression of the leg vessels through the cuffs started from distal to proximal in early diastole and then rapid deflation to the cuffs at the onset of systole.

The diastolic pressure (diastolic augmentation) increased by 93% due to rapid inflation, increasing perfusion pressure and myocardial perfusion. The Peak coronary flow velocity was measured in other clinical studies and it increases by 109%. A

decrease in systolic pressure (systolic unloading) by 15% in the aorta and coronary arteries and improved ventricular unloading is induced by the rapid cuff deflation which promotes lower extremity arterial “runoff”. Unlike the IABP, EECP also increases venous return, further promoting an increase in cardiac output.<sup>8</sup>

Patients in group A completed 35 sessions of treatment, each session is one hour per day for 5 days per week for 7 weeks, the pressure applied in this study was 220–250 mmHg. During the sessions, the patients are monitored by the responsible nurse staff and a cardiologist at the Centre.

### 2.2. Statistical analysis

The collected data were organized, tabulated and statistically analyzed using the Statistical Package for the Social Sciences software (SPSS, Chicago) version 22. For quantitative data, the range, mean and standard deviation were calculated. For qualitative data, the comparison between two groups and more was done using Chi-square test ( $\chi^2$ ). For comparison between means of two groups of parametric data, student t-test was used.

## 3. Results

There were 42 patients included in the study, 20 patients in group A and 22 in group B. Both groups were comparable and showed no significant differences in demographic data, patient’s risk factors, and a number of grafts in their CABG surgery (Table 1).

Table 2 summaries the changes in clinical variables regarding LVEF, the frequency of angina attacks per week, the frequency for sublingual nitrates per week; CCS and NYHA class at the start of the treatment and after 3 months follow up in each group.

Table 3 shows the comparisons between both groups regarding the same clinical variables as well as the rate of hospitalization if needed for any of the patients in either group during the period of follow up.

Figs. 1 and 2: summaries the clinical changes in CCS and NYHA class between patients in both groups.

## 4. Discussion

Medical treatment only for patients with angina and ICM who survived complex or diffuse coronary artery disease after CABG is associated with poor prognosis and poor quality of life during their follow up period.<sup>9–11</sup>

The selection of patients with severe ischemic cardiomyopathy for surgical revascularization is complex and involves the consideration of many clinical variables with a good estimation of both expected morbidity and mortality outcome especially in re-intervention scenarios.<sup>12</sup>

In our practice, when we discuss the available lines of treatment in such group of patients, they always asking for a none or less invasive treatment modality with zero or lowest side effects to improve their angina symptoms and their functional class especially those who experienced morbid out come after surgery.

In our study, we decided to study the effect of EECP in our patients with ischemic cardiomyopathy and suffering from angina in comparison to another group of patients who received the medical treatment only in the form of nitrates, beta-adrenoreceptor antagonists, calcium channel blockers, diuretic, ACE and aspirin.

Despite EECP is a U.S. Food and Drug Administration approved therapy as noninvasive therapy for patients with coronary artery disease and suffering from refractory angina as well as it received Class II a recommendation in European Society of Cardiology Guidelines for the Management of Stable Coronary Artery Disease, 2013,<sup>13,14</sup> yet in Egypt there is a very few centres have such a

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