Efficacy of enhanced external counterpulsation: our experience

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Submitted: 29 August 2014
Accepted: 23 September 2014
Published online: 14 November 2014

Aims
Enhanced external counterpulsation therapy is a non-invasive, non-pharmacological outpatient treatment option for refractory angina pectoris. Our aim is to evaluate its efficacy in Nepalese refractory angina pectoris patients.

Materials and methods
It was single centre prospective study conducted from 2010 August to 2013 December. All thirty one (n=31) consecutive patients, referred for and received 35 hours of treatment were included in this study. The distance covered in six minute walk test before and after the treatment was recorded and compared. Patients were followed each with the questionnaires about their anginal symptoms before and after the treatment.

Results
In our study 19(61.3%) were male and 12(38.7%) female. The mean age was 65.7±9.3 years. Most patients had multi vessel disease. Twelve patients had previous history of revascularization. In 6 minute walk test there was significant difference in mean distance covered before and after the treatment. Most patients experienced decrease in the angina symptom. They had decreased in severity and frequency of angina, resulting in decreased use of sublingual nitrates.

Conclusion
EECP can be safe and effective treatment option for patients with RAP.

Keywords
Enhanced external counterpulsation • Refractory angina pectoris

Introduction
Enhanced external counterpulsation (EECP) therapy is a non-invasive, non-pharmacological outpatient treatment option for chronic stable angina that is refractory to optimal anti-anginal medical therapy and without options for revascularization, commonly referred to as refractory
angina pectoris (RAP) [1]. EECP can improve exercise tolerance; ameliorate symptoms [2, 3] and quality of life [4] in patients with RAP [5]. EECP has been given IIa Class of Recommendation in the 2013 European Society of Cardiology (ESC) Guidelines on the Management of Stable Coronary Artery Disease [6] for RAP patients. In December 2013 The Food and Drug Administration (FDA) issued a final order to reclassify EECP for treatment of RAP, which is a preamendments class III device, into class II [7].

Our aim is to evaluate the efficacy of EECP in RAP patients in Shahid Gangalal National Heart Centre, Kathmandu, Nepal.

Materials and methods

It was single centre prospective study conducted from 2010 August to 2013 December in Shahid Gangalal National Heart Centre (SGNHC), Kathmandu, Nepal. The study protocol was approved by the Ethics Committee of SGNHC. Informed consent was taken from patients and patient party. Unless for emergency purpose medical therapy was not changed during the EECP treatment.

Thirty one (n=31) consecutive patients, referred for EECP were included in this study. Before patients were included all the contraindication of EECP therapy were ruled out. One patients was excluded from that study as the treatment was stopped due to frequent ventricular ectopic. Patients’ data, which had been recorded prior to treatment, included age, gender, past history of diabetes mellitus (DM), hypertension, dyslipidaemia, tobacco consumption, previous angiographic data (angiographic score as Single (SVD)-, double (DVD)-or triple (TVD)-vessel disease) and previous revascularization therapy. A six minute walk test was performed under the same circumstances for all the patients at baseline and at the end of the treatment. The distance covered in six minute was recorded and compared. Each patient were followed with the questionnaires about their anginal symptoms before and after the treatment.

EECP equipment was supplied by Vamed Company (Guangzhou, China).The equipment consists of an air compressor, a console, a treatment table and two sets of three cuffs. Before a treatment session, cuffs are wrapped around the patient's legs, one set on each leg. Using compressed air, pressure (260–350mmHg of external pressure) was applied via the cuffs to the patient’s lower extremities in a sequence synchronized with the cardiac cycle. In early diastole, pressure was applied sequentially from the lower legs to the lower and upper thighs to propel blood back to the heart. At end-diastole, air was released instantaneously from all the cuffs to remove the externally applied
pressure, allowing the compressed vessels to reconfirm, thereby reducing vascular impedance. Daily one hour treatment sessions were administered for a total treatment course of 35 hours.

The two-tailed paired t-test was used to evaluate the significance of improvement in the distance covered in six minute walk test before and after the treatment.

Results

Thirty one patients completed 35 hours of treatment within 7 weeks. Demographic and clinical characteristics of the patients are shown in Table 1 below. The mean age was 65.7±9.3 years. Among the 31 patients were included in this study 19(61.3%) were male and 12(38.7%) female. Twenty three (74.1%) patients had TVD, 8 (25.9%) with DVD in coronary angiogram. Seven (22.5%) patients had undergone Coronary Artery Bypass Graft (CABG), four (12.9%) individuals had undergone percutaneous coronary intervention (PCI) with stenting and one (3.2%) patient had undergone CABG as well as PCI. Among risk factors for Coronary artery disease, hypertension was present in 26(83.8%) cases, diabetes mellitus in 12(38.7%) individuals, and 12 (38.7%) were tobacco consumers. Low LVEF defined as LVEF ≤ 40% was present in two (6.4%) patients.

Table 1. Baseline demographic and clinical characteristics: N= 31 (%)

<table>
<thead>
<tr>
<th></th>
<th>Mean Age</th>
<th>65.7±9.3 years</th>
</tr>
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<tbody>
<tr>
<td>Male /Female</td>
<td>19/12</td>
<td>(61.3/38.7)</td>
</tr>
<tr>
<td>Medical history</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>26</td>
<td>(83.8)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>12</td>
<td>(38.7)</td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>12</td>
<td>(38.7)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAD TVD</td>
<td>23</td>
<td>(76)</td>
</tr>
<tr>
<td>CAD DVD</td>
<td>8</td>
<td>(24)</td>
</tr>
<tr>
<td>Post CABG</td>
<td>7</td>
<td>(22.5)</td>
</tr>
<tr>
<td>Post PCI</td>
<td>4</td>
<td>(12.9)</td>
</tr>
<tr>
<td>Post CABG+Post PCI</td>
<td>1</td>
<td>(3.2)</td>
</tr>
<tr>
<td>Low LVEF (LVEF≤40%)</td>
<td>2</td>
<td>(6.4)</td>
</tr>
</tbody>
</table>
In 6 minute walk test there was significant difference in mean distance covered before and after the treatment. Compared to baseline, 29 patients noted an increase in the 6 min walk test distance by more than 150 feet. Though there was an increase in the distance covered in 6 minute walk test distance in all patients, 30 patients experienced decrease in the angina symptom. Based on the questionnaires, except one patient, all patients noticed the decrease in severity and frequency of angina, resulting in decreased use of sublingual nitrates. Table 2 shows, as compared to the baseline, there was a significant improvement in distance covered in 6 min walk test.

Table 2. Comparison in 6 min walk test distance covered mean±standard deviation

<table>
<thead>
<tr>
<th></th>
<th>Pre EECP</th>
<th>Post EECP</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 min walk test distance</td>
<td>817.2±362.4</td>
<td>1053.4±346.4</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Though three patients developed blisters in the legs, two developed ecchymosis during the treatment, treatment was completed.

**Discussion and Conclusions**

Our study shows that EECP can be effective in RAP patients. The decrease in the angina symptoms, severity, intensity and nitrates use proves its efficacy in these patients. In the first and also the only multicentre, prospective, randomized, blinded, placebo controlled trial, Multicentre Study of Enhanced External Counter Pulsation (MUST-EECP), patients undergoing active counter-pulsation had a significant decrease in angina episodes, but there was no significant improvement in the duration of the exercise test [8].

In an EECP consortium, among 2 284 patients, an improvement was reported in up to 74% of patients by one or more CCS functional classes. The younger patients had a greater likelihood of improvement [8]. Patients who were younger, male, without multi-vessel coronary or non-cardiac vascular disease and non-smokers were likely to have higher diastolic augmentation and greater reduction in angina class after EECP. [9]

As in our study, efficacy of EECP was proven by numerous studies done in the US [10, 11, 12], Sweden [13] and Iran. [14] EECP has shown to provide long- term symptom relief and improved quality of life in a heterogeneous group of patients with ischaemic heart disease. [15] Though tobacco
use and previous myocardial infarction were associated with early relapse in angina in spite of an initial response other baseline factors studied did not affect the outcome of EECP treatment. [16]

EECP increases diastolic aortic pressure, reduces systolic pressure and enhances venous return, thus resulting in increased cardiac output. [17] However, the mechanisms by which these hemodynamic effects lead to a reduction of angina are poorly understood, although the acute effect is similar to IABP. [18] There is accumulating evidence suggesting that EECP treatment improves endothelial function, which may contribute to the clinical benefit. [5] EECP treatment is associated with an immediate increase in blood flow in multiple vascular beds including the coronary arterial circulation. [18] This increase in blood flow may result in increased endothelial shear stress which enhances endothelial function by stimulating the release of the vasodilatory mediator nitric oxide and reduces the release of the vasocontractile endothelin-1. [17, 20, 21, 22] Furthermore, besides the release of metabolites from ischemic regions, an increase in endothelial shear stress is considered a major stimulus for collateral blood vessel development and recruitment. This suggests that EECP treatment may exert its clinical beneficial effect by enhancement of coronary collateralization. EECP therapy has been associated with the release of angiogenic factors, such as vascular endothelial growth factor [23], basic fibroblast growth factor and hepatocyte growth factor. [22]

Our study limitations are single centre, non-randomized study with a small number of patients.

Our study demonstrates, EECP can be effective in decreasing the severity and intensity of angina pain. It is also helpful in improving the effort tolerance and the quality of life in patients with RAP.
Statement on ethical issues

Research involving people and/or animals is in full compliance with current national and international ethical standards.

Conflict of interest

None declared.

Author contributions

All authors contributed to the writing of the manuscript and analyzed the data, C.M.A. drafted the manuscript. All authors read and met the ICMJE criteria for authorship, agree with manuscript results and conclusions and approved the final manuscript.

References


