RESEARCH ARTICLE

Investigation of enhanced external counter pulsation of blood pressure-elevating effect on chronic heart failure patients with low blood pressure

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Abstract

Objective: To explore and evaluate the clinical effect of enhanced external counter pulsation in the treatment of patients with chronic heart failure and low blood pressure.

Method: The retrospective study was conducted from January, 1, 2023, to January 31, 2024, at the Department of Cardiology, The First Affiliated Hospital of Zhejiang Chinese Medical University, China, and comprised data from January to October 2023 of chronic heart failure in patients who also had low blood pressure. The patients were divided into two groups on the basis of the treatment received. Group A patients had been treated with enhanced external counter pulsation, while group B patients had been asked to do regular exercises. Both the groups had been treated for cumulatively 35 hours. The change in blood pressure was the main outcome measure, and it was measured at baseline and 24h after treatment. Data was analysed using SPSS 20.

Results: Of the 111 patients, 61(55%) were in group A; 36(59%) females and 25(41%) males with mean age 59.33±9.01 years. There were 50(45%) patients in group B; 29(58%) females and 21(42%) males with mean age 56.47±11.23 years. Baseline systolic blood pressure was not significantly different between the groups ($p>0.05$). Post-intervention, both the groups showed significant increase in in systolic blood pressure ($p<0.05$), but the change from baseline was more significant in group A compared to group B ($p<0.05$).

Conclusion: Enhanced external counter pulsation had a significantly better therapeutic effect in the treatment of patients with chronic heart failure and low blood pressure.

Key Words: Enhanced external counter pulsation, Heart failure, Low blood pressure, Cardiac rehabilitation.

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Introduction

Chronic heart failure (CHF) has become a severe global public health burden that is characterised by an increasing incidence of rehospitalisation and high mortality rates. Most CHF patients have normal blood pressure (BP), but studies showed that there were 24% patients with low BP[1], which might correlate with a higher incidence of arrhythmia, renal dysfunction and diabetes[2]. It also pushes physicians into a clinical dilemma because some medications cannot reach the therapy criteria for long-term low BP. Some vasopressor medications, like Midodrine, could probably elevate the BP, but they could also bring about several side-effects that have been associated with increased mortality in such patients[3].

Enhanced external counter pulsation (EECP) is a non-invasive treatment designed for patients with symptomatic angina pectoris, and has been demonstrated to augment diastolic flow, raising diastolic BP (DBP). Evidence suggests that EECP may enrich the myocardial oxygen saturation and strengthen the cardiac output[4-5].

The current study was planned to explore and evaluate the clinical effect of EECP in the treatment of CHF patients having low BP. The null hypothesis was that EECP would elevate the systolic BP (SBP) in the patients.

Materials and Methods

The retrospective study was conducted from January, 1, 2023, to January 31, 2024, at the Department of Cardiology, The First Affiliated Hospital of Zhejiang Chinese Medical University, China, and comprised data from January to October 2023 of CHF inpatients who also had low BP. The patients were divided into two groups on the basis of the treatment received. Group A patients had been treated with EECP, while group B patients had been asked to do regular exercises.

After approval from the institutional ethics review board, the sample size was calculated using the formula $N=[2\times(Z\alpha+ Z\beta)2\times\sigma2/(\mu2-\mu1)^6$, with $\alpha=0.05$, $\beta=0.10$, $Z\alpha=1.96$, $Z\beta=1.28$ and $\sigma=4.19$, while estimating group A

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BP variation to be μ1=8mmhg, and group B variation to be μ2=5mmhg. The sample size was inflated to cover for dropouts. The expected effect size and variability were estimated on the basis of preliminary data and relevant literature[7].

The sample was raised using consecutive sampling technique. Those included were CHF patients diagnosed on the basis of the Diagnostic Criteria for Heart Failure[8], and classified as New York Heart Association (NYHA) class I with echocardiography showed reduced myocardial movement and left ventricular ejection fraction (LVEF) ≤55%. The patients could do regular rehabilitation exercises guided by skilled physicians, and had normal communication ability and mental state. Patients excluded were those with concomitant diseases, like moderate to severe aortic valve regurgitation, dissecting aortic aneurysm, significant pulmonary arterial pressure or infectious diseases, and those using anticoagulants, had an international normalised ratio (INR) >2.0, congenital heart disease, hypertrophy cardiomyopathy, active phlebitis, venous thrombosis, uncontrolled arrhythmia, and atrial fibrillation. Also excluded were pregnant women. Informed consent had been taken from all the patients at the time of treatment. Data of patients who had to quit from the EECP group for various reasons, like skin chafe or muscle soreness, was also excluded.

Clinical baseline profiles included sex, age, body mass index (BMI), systolic blood pressure, educational background and employment situation. Information like BP were collected by writing form designed by our team and other data like medical history were collected by reviewing electronic medical system, and then we put the records into the excel data base after selection.

All the patients in both the groups received relevant medicine treatment, including beta-blockers, angiotensin-converting enzyme inhibitors/angiotensin II receptor blockers (ACEIs/ARBs), aldosterone receptor antagonists, diuretics, nitrates and anti-platelet drugs, adjusted as per individual need. The patients the treatment regimen 3-5 times a week for a total of 35 hours. Those who could not complete 35 hours of treatment were excluded.

Group A patients received EECP therapy in sessions lasting 30-60 minutes every two days. EECP involved continual inflation and deflation of compressible cuffs wrapped around the patients' thighs. Air pressure was applied by the cuffs to the thighs in a continuous synchronised manner with the cardiac cycle via electrocardiogram (ECG) signals. The patients' ECG was monitoring throughout the treatment.

Group B patients were asked to do exercise every two days at home, including Tai chi, city-walk, jogging, swimming or others determined as per their preferences. BP readings were taken on the 5th-7th day after the intervention.

Data was analysed using SPSS 20. Qualitative data with normal distribution was presented as mean ± standard deviation, and it was compared using the student's t-test. Baseline and post-intervention values were compared using paired t-test. Skewed data was presented as median (min-max), and it was compared using the Mann–Whitney U test. Quantitative data was presented as frequencies and percentages; it was compared using the chi-square or Fisher's exact test. P<0.05 was considered statistically significant.

Results

Of the 144 patients enrolled, 111(%) completed the study (Figure 1). Of them, 61(55%) were in group A; 36(59%) females and 25(41%) males with mean age 59.33±9.01 years. There were 50(45%) patients in group B; 29(58%) females and 21(42%) males with mean age 56.47±11.23 years (Table). The baseline SBP of group A and B patients was 91.46±5.18mmhg and 92.17±5.12mmhg, respectively (p>0.05). Post-intervention, the SBP of group B rose to 94.58±4.19mmhg (p<0.05), while that of group A rose to

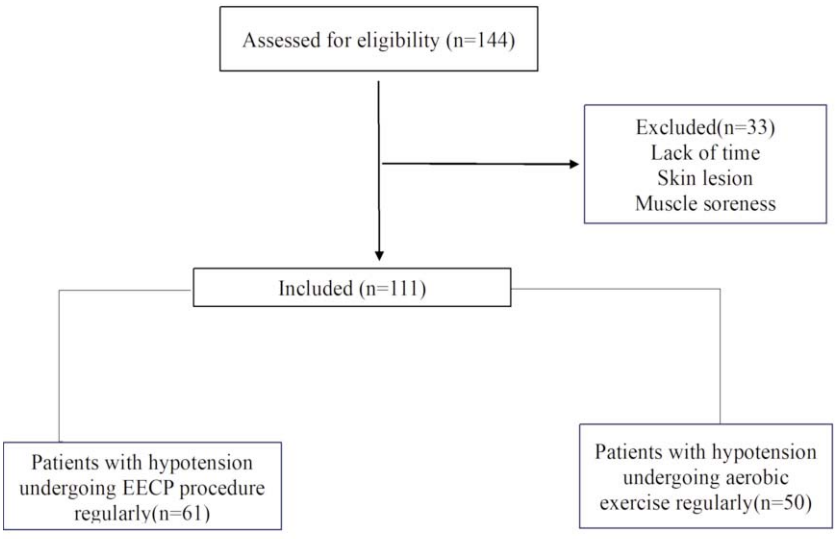

Figure: Study flowchart.

Table-1: Patient characteristics.

Clinical characteristics	EECP group (n=61)	Control group (n=50)	P value
Age (years)	59.33±9.01	56.47±11.23	0.064
Male	25(40.98)	21(42.0)	0.914
Body mass index (kg/m^2)	16.66±0.65	16.94±1.20	0.067
Education (years)	5.38±1.92	5.27±1.87	0.701
Employed	19(31.15)	23(46.0)	0.108
Baseline SBP	91.46±5.18	92.17±5.12	0.329
Post-intervention SBP	100.72±8.00	94.58±4.19	0.00

EECP: Enhanced external counter pulsation, SBP: Systolic blood pressure.

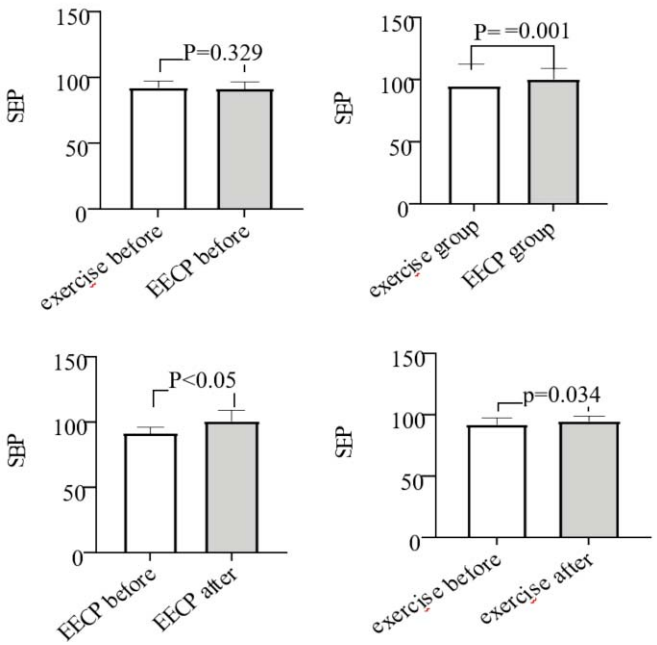

Figure-2: Intragroup and intergroup comparison of change in systolic blood pressure (SBP) at baseline and post-intervention.

100.72±8.00mmhg (p<0.05). The change from baseline was more significant in group A compared to group B (p<0.05) (Figure 2).

Discussion

CHF is a complex disease with a high incidence rate of rehospitalisation, morbidity and mortality. Some studies showed that CHF mortality was around 24.5% and there were severe complications leading to a poor life quality[9]. More specifically, CHF is usually accompanied by low BP (CHF-LBP) causing much higher in-hospital and post-discharge mortality compared to CHF patients with normal BP[10]. Those presenting with low SBP generally have hypo-perfusion symptoms, like low body mass, weak pulse, cold extremities, and a very poor prognosis[11]. Such patients often have other thorny comorbidities, like chronic kidney disease (CKD), diabetes and coronary artery disease (CAD), that make perfusion ineffective over a long period of time[12]. physicians are more likely to prescribe the positive inotrope medicine for these patients, but, even the short-term usage of such agents may increase in-hospital and post-discharge mortality, especially in patients with CAD[13-14]. Therefore, there remains an urgent need to develop an approach that may safely improve carbon monoxide (CO) levels without affecting BP, heart rate and coronary perfusion in such patients.

EECP is a non-invasive treatment for stubborn angina pectoris, particularly for CAD patients. Some studies showed that EECP could significantly increase blood flow and augment shear stress in peripheral and central vascular beds which might have a favourable effect on DBP[15-16].

In the current study, EECP group had baseline SBP 91.46±5.18 mmhg which rose to 100.72±8.00 mmhg after EECP. The EECP device pressurises the lower body, including buttocks, lower legs and thighs, during the cardiac diastole, driving the fluid back to the cardiovascular system. Due to the large volume of fluid, including venous blood and lymph counter-flow from the lower body, it could improve the blood supply of the cardiovascular system. Therefore, it could increase stroke volume, and also a corresponding increase in the cardiac output, which is beneficial for elevating SBP in such patients[17].

Meanwhile, a study showed that circulating levels of cluster of differentiation-34 (CDR34), KDR (kinase insert domain receptor ,also known as VEGFR2) that is a receptor tyrosine kinase, and a key surface marker used to identify and isolate endothelial progenitor cells (EPCs) and EPCs (CD34+/KDR+EPCs) in patients who received the EECP treatment were significantly higher than the control group, which implied that EECP might be beneficial for maintaining the BP because EPCs that were derived from stem cells could proliferate and differentiate into endothelial cells in the vascular system, which has an important role in the repair of vascular function and structure in chronic cardiovascular diseases[18]. Also, EECP could improve endothelial cell stabilisation by regulating the release of nitrogen oxide (NO) and endothelin-1 (ET-1) through vascular shear stress that has a long-term advantage in patients with low BP[19-20]. The SBP elevations observed in the current study may have clinical significance in regard to improving the SBP in these patients.

The current study showed that regular exercise might also

be conducive to elevating SBP in these patients. It perhaps relates to increasing cardiac output by activating the sympathetic system and fortifying the musculoskeletal strength which could also increase the shear stress and benefit these patients for a long time, especially for patients with heart failure, after professional evaluation[21]. However, exercise may also cause some discomfort to these patients. For instance, some patients may have muscle strain injury or trigger arrhythmia during inappropriate exercise, and it also has the risk of inducing acute heart failure attacks without close monitoring. Compared to exercise, patients can get close monitoring of the heart rate, rhythm, oxygen saturation and BP during the EECP procedure, thus it greatly decreases such adverse events occurring and is much safer at rehabilitation centres. Post-intervention SBP in the EECP group improved significantly more the exercise group in the current study. It might correlate to the fact that the EECP patients usually had a strict treatment plan with physicians, while patients in the exercise group might have modified the designated training plan during the period.

Clinically, the current study showed that EECP might be a promising approach and might improve the survival rate and life quality. However, during the treatment, some patients withdrew from the EECP group because of skin lesions or muscle soreness, and, therefore, physicians should be aware of such complications in advance and should choose appropriate sleeves, and place and wrap soft pads appropriately in the protruding parts, like the bones, as a precaution.

The current study has several limitations. First, the definition of low BP is still in dispute, and the study chose a compromised standard[22-23]. Second, the data was drawn from a small number of CHF patients in a stable condition. The possibility of selection bias was not excluded. Also, the study could not determine whether the outcome of EECP was transient or persistent, because the study only included short-term data.

Conclusion

EECP was found to be a potential approach that could be used in CHF patients with low BP without increasing myocardial oxygen demands, like inotrope agents, and might be a valuable component of CHF rehabilitation. Clinically, EECP should be applied to CHF patients with low BP in future clinical practice to improve their survival rate and life quality.

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Conflict of Interest: None.

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CB, SJ & QQ: Concept and design.
JW & GQ: Data acquisition and analysis.
QY & CJ: Final approval and agreement to be accountable for all aspects of the work.