

ENHANCED EXTERNAL COUNTERPULSATION IN THE TREATMENT AND REHABILITATION OF CORONARY PATIENTS IN INDONESIA



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ABSTRACT

We report our experience using the new noninvasive treatment for coronary patients called enhanced external counterpulsation (EECP). Thallium-201 stress scintigraphy and treadmill test were done before and after 36 sessions of EECP treatment on 38 coronary patients.

The results showed significant ($P < 0.01$) improvement in perfusion as well as exercise tolerance in 86.8% and 94.2% of patients, respectively. The symptoms of angina pectoris and functional classes of the patients also showed significant ($P < 0.05$) improvement. All patients tolerated the treatment without serious complications.

The magnitude and rate of increased exercise tolerance achieved by EECP treatment was greater than those achieved by training after coronary bypass surgery (CABG) or exercise training rehabilitation program for the matched coronary patients reported by others^{7,8}.

The mean double products (DP) from the treadmill test results of the improved Tl-201 perfusion subgroups decreased significantly ($P < 0.001$). On the contrary, the DP of the unimproved subgroup increased significantly ($P < 0.001$). This could mean improvement in efficiency of the heart in the former, that is, more work was done with lower pressure-pulse products.

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INTRODUCTION

Enhanced external counterpulsation (EECP) is a noninvasive treatment for acute and chronic ischemic heart diseases. The device consists of three pairs of big air cuffs wrapped tightly around the patient's legs, thighs, and buttocks. Controlled by microcomputer technology, the cuffs inflate and deflate automatically during diastole to strongly squeeze blood from the sequentially distal proximal lower extremities and buttocks back toward the aorta. The retrograde flow in the aorta greatly increases the

pressure and volume of perfusion during the diastolic phase above the systolic pressure (so the diastole/systole pressure ratio is greater than 1.2) in the tributaries of the aorta especially to the coronary circulation¹. The EECP device has undergone remarkable technical improvement since the cooperative clinical trial involving 25 institutions² enabling the diastolic augmentation wave to greatly surpass the systolic wave in amplitude as well as area under the curve of finger plethysmographs^{1,3}. The action of counterpulsation has been reported to open collateral vessels, which in turn improves acute and chronic cardiac ischemic signs and symptoms^{2,3} including those not amendable to other treatment modalities⁴.

PATIENTS AND METHOD

The research was done at the National Cardiac Center of Indonesia, RS Jantung "Harapan Kita" in Jakarta.

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We used the same type of device (EECP Shuangshan brand) as the Stony Brook (SUNY) team⁴ in the treatment of 38 coronary patients with stable angina.

The inclusion criteria were: 1) patients with stable angina pectoris, referred to the EECP Department of The National Cardiac Center "Harapan Kita" during the period of December 1, 1992 to August 31, 1993 undergoing medical treatment (some had undergone percutaneous transluminal coronary angioplasty (PTCA) or coronary artery bypass graft (CABG) before); 2) patients who were willing to cooperate by signing a consent form approved by our hospital's clinical research department; and 3) patients with proven myocardial ischemia based on TI-201 scintigraphy.

The exclusion criteria were patients suffering from congestive heart disease (EF less than 50%), aortic valve insufficiency, recent myocardial infarction (less than 3 months), significant arrhythmia (10 or more VES per minute), severe peripheral vascular disease, thrombophlebitis, hypertension greater than 170/110 mmHg, hemorrhagic diathesis, valvulopathy, cardiomyopathy, congenital heart ailment, or infections in the lower limbs or buttocks.

During the EECP treatment period patients were instructed to take their usual medications without making significant changes. Each session of EECP treatment took 1 hour, and all patients undertook a full course of 36 sessions⁴.

The statistical analysis used were chi-square test and Fischer exact test (the latter when chi-square test was inapplicable) for ordinal scales and paired *t* test for interval scales.

RESULTS

During the trial period, 92 patients were referred to the EECP department, 38 of whom fulfilled the requirements for this trial. The patients were all male, except 2; their mean age was 56.31 ± 1.24 (SD) years, ranging from 43 to 73 years old. All were evaluated with TI-201 perfusion scintigraphy and 35 underwent treadmill stress test using Bruce protocol before and after EECP treatment.

The segmental assessment of the TI-201 imaging results was done as described by Okada⁵, that is, 9 segments from 3 projections (anterior, LAO 40° and LAO 70°) were evaluated. The images were classified into either one of the following gradations of perfusion: normal washout, slow washout, transient defect, partial redistribution, and persistent defect. There were 342 segments of myocardium analyzed with distribution as shown in Table 1. The shift toward improvement was statistically significant ($P < 0.01$; chi-square test; d.f. = 4).

Nine patients (23.6%) showed complete improvement of myocardial perfusion; the previously ischemic segments became completely normal after EECP treatment. Five

TABLE 1. SHIFT IN FREQUENCY DISTRIBUTION BETWEEN PRE- AND POST-EECP TI-201 PERFUSION SCINTIGRAMS.

	TST Scintigrams					Total
	A	B	C	D	E	
Pre-EECP	168	48	58	40	28	342
Post-EECP	219	31	47	34	11	342
Total	387	79	105	74	39	684

The difference in frequency distribution of the TST scintigrams between pre-EECP and post-EECP was statistically highly significant ($P < 0.01$; chi-square test; d.f. = 4).

EECP = Enhanced External Counterpulsation, TI-201 = Thallium 201, TST = thallium stress test; the classifications A, B, C, and D are based upon segmental analysis of 3 projections of the myocardium⁵. A = normal washout, B = slow washout, C = transient defect, D = partial redistribution, E = persistent defect

patients (13.2%) had post-EECP myocardial perfusion scintigrams that did not improve. The other 24 patients' myocardial perfusion scintigrams showed partial improvement. Three (7.9%) patients whose treadmill tests, either pre-EECP or post-EECP, were not performed were excluded from the analysis.

From the results of the completed treadmill test on 35 patients, we found an impressive mean rise in aerobic capacity of $+1.16 \pm 0.32$ Mets, from pre-EECP 6.89 ± 0.21 Mets to 8.04 ± 0.41 Mets ($P < 0.01$; 2-tailed paired *t* test).

The mean duration of treadmill test (Bruce protocol) withstood by the patients increased from 5.73 minutes pretreatment to 7.08 minutes after 36 sessions of EECP ($P < 0.01$, 2-tailed paired *t* test).

The angina symptoms produced by exercise on treadmill underwent significant ($P < 0.05$; chi-square test) improvement. Before EECP there were 14 (40%) patients who had angina pectoris as the terminating cause of their treadmill test, however, after EECP it was reduced to 5 (14.28%) out of 35 patients.

The shift toward improvement in distribution of their New York Heart Association (NYHA) functional class between pre-EECP and post-EECP was also statistically significant ($P < 0.05$, chi-square test, d.f. = 1), as shown by Table 2.

The rise in exercise tolerance occurred in all the other patients except 1 (2.9%) that decreased (the test was terminated because of hypertensive response) and another that remained the same.

The overall mean double-products (DP) of the treadmill test results showed insignificant ($P > 0.05$) change, that is, 23459.72 ± 1047.17 to 23250.56 ± 812.23 . The DP changes of separate subgroups were mutually opposing. The 9 patients who underwent complete improvement of myocardial perfusion had their DP decreased from 25166 ± 4609.26 to 24503.33 ± 4012.03 ($P < 0.001$), the 21

TABLE 2. SHIFT IN FREQUENCY DISTRIBUTION BETWEEN PRE- AND POST-EECP FUNCTIONAL CLASSES (NYHA).

	Functional Classes				Total
	I	II	III	IV	
Pre-EECP	13	14	8	0	35
Post-EECP	23	12	0	0	35
Total	36	26	8	0	70

The difference in frequency distribution of the functional classes (NYHA) between pre-EECP and post-EECP was statistically significant ($P < 0.05$; chi-square test; d.f. = 1; columns II to IV were combined to make chi-square calculation possible).

EECP = Enhanced External Counterpulsation, NYHA = New York Heart Association

patients with partial improvement of myocardial perfusion had DP decreased from 22910.48 ± 6193.11 to 21644.29 ± 4227.46 ($P < 0.001$), while the patients who did not show improvement in myocardial perfusion had DP increased from 23392 ± 4470.75 to 26908 ± 5738.59 ($P < 0.001$).

DISCUSSION AND CONCLUSION

Our experience was similar to that reported by the SUNY team⁴, although our patients were more functionally disabled at base line based on their initial exercise tolerance and had a proportionately greater functional (aerobic) gain after EECP treatment.

From the results of treadmill tests it was apparent the rise in exercise tolerance was 16.8% after 7 weeks of treatment. As a comparison, Adams et al⁷ reported only a 10% rise in exercise tolerance in coronary artery bypass patients (mean age 53.7 years) after being trained 3 days per week, 40 minutes per day for 12 weeks by walking and jogging at 75 to 85% maximum heart rate; while Wilmore⁸ reported a +14.9% change in $V_{O_2\max}$ (initial value 28.2ml/kg/min or 8 Mets) in 44 middle-aged men after doing prescribed exercise for 3 months. Thus, EECP could be regarded as a safer and more effective accelerator or adjunct for the rehabilitation program of coronary patients. Moreover, the scintigraphic improvements shown after EECP treatment could not have been produced by exercise⁹. During the period of EECP treatment, we did not prescribe coronary exercise to our patients.

The overall analysis of the DP from the treadmill tests did not show significant change. However, upon separate analysis of the subgroups, it was apparent the subgroups whose TI-201 scintigrams underwent complete or partial resolution of the ischemic areas showed highly significant

decrement ($P < 0.001$), while the subgroup whose TI-201 scintigrams did not improve showed highly significant ($P < 0.001$) increment. This could mean improvement in heart efficiency in the improved myocardial perfusion subgroups, that is, more work could be done with less effort of the heart.

Based upon the data, we postulated that the improvement in quality of life and exercise capacity of patients was the result of better perfusion of myocardium through microcollaterals opened up by EECP treatment, as shown by their thallium stress test results.

In conclusion, the results indicate that EECP treatment is an effective adjunct for treatment and rehabilitation of coronary patients with stable angina, a reliable and safer alternative to invasive techniques (especially for patients who refuse operations or PTCA), or in institutions where such facilities are not available.

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