Role of enhanced external counterpulsation in angina treatment

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Abstract Enhanced external counterpulsation (EECP) is a noninvasive procedure in which compressions are applied to the vascular beds within the muscles of the legs, thighs, and buttocks in a sequential manner, progressing from the calves upward. Prompted by favorable results with EECP in Chinese angina patients, we studied the efficacy of the technique in 18 patients with chronic stable angina and evidence of exertional ischemia by thallium-201 perfusion imaging. Patients received 1 hour of EECP therapy daily for a total of 36 hours. Treatment with EECP produced substantial improvements in symptoms in all 18 patients and reduced myocardial ischemia, as assessed by thallium scanning, in 14 patients. Follow-up of 17 patients showed that the subjective and objective benefits of EECP were maintained for at least 3 years in most patients. In selected angina patients, EECP should be seriously considered as part of the treatment program.
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Studies carried out 20 years ago demonstrated that external counterpulsation may possibly improve survival in patients with cardiogenic shock after myocardial infarction (MI) and also may reduce mortality shortly after infarction.[1,2] Although this noninvasive procedure is not new, it has been modified sufficiently in recent years to warrant reevaluation by clinicians who treat patients with chronic angina.

External counterpulsation involves the inflation of a series of compressive balloons, with compressions triggered to the patient's ECG (Figure 1). The device increases myocardial oxygen supply by increasing diastolic perfusion pressure and reduces cardiac workload by decreasing left-ventricular afterload.[3] In the early 1980s, Chinese investigators reported on their extensive experience in treating angina patients with an enhanced version of the device (which uses three cuffs rather than two and sequential calf-to-thigh counterpulsation).[4] These favorable results prompted us to assess the efficacy of enhanced external counterpulsation (EECP) in producing sustained benefits in US patients with chronic angina. In this brief review, we summarize our experience with this promising technique.

STONY BROOK STUDIES

The purpose of the Stony Brook studies was to determine whether EECP could alleviate the symptoms of patients with chronic angina and produce a sustained increase in the perfusion of the ischemic myocardium. In other words, we wanted to find out whether the hemodynamic changes produced by EECP result in a sustained reduction in exertional ischemia and anginal symptoms, as well as an improvement in exercise tolerance. To address these issues, thallium imaging was used to document the degree of exertional myocardial ischemia before and after EECP treatment. The change in functional status after EECP was assessed by symptom-limited stress testing.

Enhanced external counterpulsation was performed by compressing the vascular beds within the muscles of the legs and thighs, including the buttocks, in a sequential manner, progressing from the calves to the lower and then upper thighs. The compression is accomplished by introducing air into the three sets of balloons. The timing of the compression is controlled by the patient's ECG, so that increased blood flow and blood pressure will reach the coronary vessels during diastole at the time of lowest intramyocardial tension. In addition, compression of the venous bed of the lower ex-

One possible mechanism for the improvements seen after EECP is that the procedure may open or enhance the development of collateral channels.

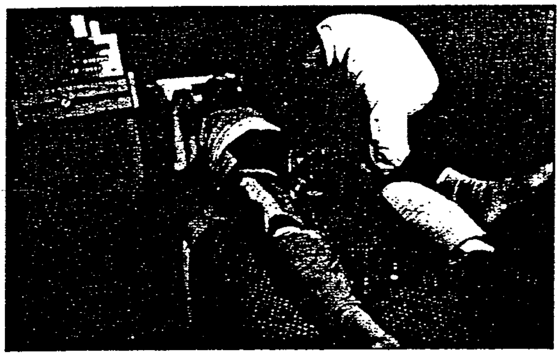

FIGURE 1. Enhanced external counterpulsation device. Photo courtesy of Future Medical Products, Inc., Hauppauge, NY.

tremities increases venous return and cardiac output. The external pressure is then released during systole, causing systolic unloading and decreasing cardiac workload.

Initial studies

In our initial studies conducted between 1989 and 1991, 18 patients (17 men and 1 woman) were treated with EECP for 1 hour daily for a total of 36 hours.[5] All patients were monitored hemodynamically and clinically during treatment. Diastolic augmentation pressures were progressively increased by increasing the external compression. The maximal external pressure used to maximize the diastolic/systolic pressure ratio (diastolic augmentation) was 280 mm Hg. Blood pressure waveforms were continuously monitored by finger plethysmography.

Adjustments in anginal medications were determined by patients and their physicians during the course of the study. No other therapeutic interventions were performed during the study.

After completing the course of EECP therapy, patients underwent a thallium-201 stress test (with usual medications continued); exercise duration was the same as that during baseline testing so as to provide a comparison of imaging test results. Furthermore, a maximal stress test was performed less than 1 week after EECP treatment to assess exercise tolerance.

The 18 patients chosen for study had chronic stable angina despite medical and surgical therapy, as well as evidence of exertional ischemia by thallium-201 perfusion imaging. Other patients were excluded because of clinical congestive heart failure, aortic insufficiency, MI within the previous 3 months, significant ventricular ectopic activity or atrial fibrillation, nonischemic cardiomyopathy, severe occlusive peripheral vascular disease, recurrent deep vein thrombophlebitis, systemic hypertension (> 180/110 mm Hg), or a bleeding diathesis.

Results. All 18 patients experienced substantial improvements in anginal symptoms after EECP; 16 were completely free of angina during usual activities of daily living. Thallium-201 stress testing (performed to the same exercise duration before and after EECP) showed a complete resolution of ischemic defects in 12 patients (67%), a decrease in the area of ischemia in 2 patients (11%), and no change in 4 patients (22%). Thus, 14 patients had a reduction in myocardial ischemia after EECP as assessed by thallium-201 imaging ($P < .01$).

Comparison of maximal stress test results before and after EECP showed that EECP produced a significant increase in exercise duration (from 8.14 ± 0.71 to 9.72 ± 0.77 minutes, $P < .005$) without a significant change in double product (from 22,062 ± 1,664 to 22,816 ± 1,653 mm Hg × beats per minute). Subgroup analysis of the 14 patients who showed improvement in their thallium scans after EECP revealed increases in both exercise duration (from 8.58 ± 0.66 to 10.44 ± 0.59 minutes, $P < .001$) and double product (from 21,827 ± 2,0444 to 24,842 ± 1,707 mm Hg × beats per minute, $P < .01$) during maximal stress testing after EECP.

Possible mechanism. That these patients improved after EECP was obvious, but the mechanism responsible for that improvement remains speculative. The increase in exercise time could be due, in part, to a training effect, but this could not explain the thallium finding.

Follow-up of 17 patients showed that the majority continued to experience beneficial subjective and objective effects 3 years after the initiation of EECP therapy.

One possible explanation for the improvement we observed is that EECP may open or enhance the development of collateral channels. Such a mechanism may also explain the relative lack of efficacy of EECP in patients with severe or diffuse three-vessel coronary artery disease (CAD). At least one open conduit may be necessary to enable transmission of the force and flow necessary to achieve a beneficial effect.

In the present study, patients served as their own controls. Whereas the course of CAD is largely unpredictable, regression would not be expected to occur over 6 to 7 weeks in a group of patients whose angina had been disabling or progressive over a period of months or years. The enrolled patients did not undergo any simultaneous therapy, such as diet, lipid reduction, weight loss, or smoking cessation. Dosages of antianginal medications were decreased or remained the same over the course of the study in all patients. Since the study cohort was predominantly male, no definitive conclusions regarding efficacy in women can be made.

It should be noted that EECP was well tolerated by all patients studied. No patient withdrew after enrollment, and no complications of EECP occurred.

Follow-up study

The long-term, sustained efficacy of EECP was confirmed in a recently reported follow-up study.[6] We successfully contacted 17 of the 18 patients who underwent EECP therapy in our earlier studies. At a mean follow-up of 3 years, 13 patients reported the continued absence of limiting angina; also, no MIs or other ischemic events had occurred. Furthermore, repeat thallium stress testing, performed in 10 of the 14 originally improved patients, again showed improvement from the pre-EECP test in 8 patients and worsening in only 2 patients.

CONCLUSIONS

These results indicate that 3 years after the initiation of EECP therapy, beneficial effects—both subjective and objective—are demonstrable in patients with chronic refractory angina. Thus, in selected patients, EECP should be seriously considered as part of the clinician's therapeutic armamentarium.

We are currently enlarging our data base and have now studied 70 patients. They will be the subject of future reports.

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Two stents now approved for intracoronary use

Two stents have now been approved by the FDA for use in the coronary arteries. The Gianturco-Robin stent (Cook Cardiology, Bloomington, Indiana) is indicated for the resection of post-balloon angioplasty dissection flaps. The Palmaz-Schatz stent (Johnson & Johnson, Warren, New Jersey) recently received approval for use as an initial therapy for stenosed coronary arteries in selected patients.