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New Sequential External Counterpulsation for the Treatment of Acute Myocardial Infarction

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Abstract: Over a period of 6 years, 52 patients with acute myocardial infarction (AMI) were treated with sequenced external counterpulsation (SECP). Of the 23 patients who experienced severe chest pain, 22 had complete relief within 30 min of SECP, and 31 of the 52 patients showed remarkable improvement in their electrocardiogram after the first hour of treatment. Fifteen patients were studied using the 35-lead ST segment elevation-mapping method. ΣST and NST, indicators of infarct size, showed decreasing trends in seven patients treated with SECP for a period of 6 days, whereas ΣST and NST of the control group of eight patients increased during the same period. Our hemodynamic data indicate that in four of five patients with AMI and left heart failure, the central venous pressure and cardiac output increased after SECP, whereas the pulmonary wedge pressure decreased. Measurements of the P-wave terminal force of lead V_1 also demonstrated that the application of SECP can improve left ventricular function in a majority of patients with AMI. Key Words: External counterpulsation—Buttock balloons—Echo—Myocardial infarction.

It is now well established that the incidence of pump failure and arrhythmia during the acute stages of myocardial infarction is closely related to the infarct size (1). In the initial stages of acute myocardial infarction (AMI), there is a large area of ischemic myocardium surrounding the dead necrotic center. This center expands continuously to the ischemic area within 7 days after the infarction. One major goal in the treatment of AMI lies in the prevention of the expansion of this necrotic area. Several attempts to reperfuse the ischemic area through the use of drugs have been unsuccessful.

Retroperfusion of the infarcted area, an alternative method, is difficult owing to the high irritability of the right ventricle and to the risk of ventricular fibrillation. Some studies have indicated that intraaortic balloon pumping can promote the collateral circulation of coronary arteries, thus reducing the myocardial ischemic injury (2). The intraaortic balloon pump is an invasive method and difficult to apply generally in a wide variety of cases. Therefore, the new noninvasive sequenced external counterpulsation (SECP) method was developed and evaluated as a means of rescuing the ischemic myocardium. This method employs the use of the four-limb SECP procedure with buttock balloons. The application of external pressure pulses to the arms, legs, and buttocks during diastole increases the blood supply to the coronary arteries. During systole, the pressure is released, thus lowering the vascular resistance and the pressure exerted by the left ventricle. A description of the external counterpulsation (ECP) device has been previously published (3). Our experience using this technique with 52 AMI patients is reported.

MATERIALS AND METHODS

From October 1976 to May 1982, 52 patients were treated with SECP. These patients were diagnosed as having AMI based on clinical assessment and typical changes in electrocardiogram (ECG) and serum enzyme levels. Table 1 identifies the AMI

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TABLE 1. *Age and infarct sites of 52 acute myocardial infarct patients treated with sequenced external counterpulsation*

Age of patient (years)	Location of infarct
≥71 (n = 12)	Anterior (n = 15)
61–70 (n = 15)	Extensive anterior (n = 14)
	Inferior (n = 13)
51–60 (n = 15)	Extensive anterior and inferior (n = 4)
41–50 (n = 8)	Anteroseptal (n = 3)
	Inferior and posterior (n = 1)
≤40 (n = 2)	Lateral and posterior (n = 1)
	Inferoseptal (n = 1)

patients as to their age and infarct site. In addition to the routine treatment for AMI, all patients received SECP therapy immediately on hospital arrival. The first SECP treatment lasted 2–3 h, followed by 1 h of treatment daily for 5 days. One complete course of treatment continues for a total of 6 days. The time interval from the onset of the AMI to the start of SECP therapy varied from 2 to 92 h, with an average of 28.5 h. The ECG was recorded before and after each SECP treatment. After the first course of SECP treatment, the ECG was recorded once every 2–3 days for the next 2 weeks and then once a week until the patient was discharged.

To verify the beneficial effects of SECP on the ischemic myocardium, Maroko's precordial ST segment elevation-mapping method (4) was employed to assess the size of the infarcted area during the AMI. From the 35-lead recordings, the values of ΣST, NST, ΔΣST, and ΔNST were calculated. ΔΣST and ΔNST are the mean values of the differences of ΣST and NST, respectively, between pre and post counterpulsation. Of the 15 cases studied, 7 were undergoing SECP and 8 were in a control group. The average time from the onset of the illness to counterpulsation treatment and ECG recordings was 23 h for the treated group and 7.8 h for the control group. ECGs were taken before and after treatment in the SECP group; the same procedure was used in the control group, but no SECP treatment was administered.

The central venous pressure (CVP), pulmonary wedge pressure (PWP), and cardiac index (CI) were measured in five patients with complicated left heart failure to study the hemodynamic effects of SECP. Cardiac output was measured using a flow-directed catheter and cardiac output computer (Edwards Laboratories, Santa Ana, CA, U.S.A.). The variations in the P-wave terminal force of lead V_1 (PTF-V_1) were studied before and after each SECP in a group of 34 patients.

RESULTS

General patient conditions

Of the 52 patients studied, 23 had severe chest pain before the start of counterpulsation. The other 29 patients had been treated with pain-relieving drugs before admission. In 22 of 23 cases, severe chest pain was relieved within 30 min of the initiation of treatment. Generally, in most cases, there was no recurrence of chest pain. Recurrence of chest pain in one patient disappeared with the continuation of SECP treatment. Before SECP, 18 patients had signs of circulatory collapse characterized by poor organ perfusion as evidence by cold, clammy skin, cyanosis, increased heart rate, and systolic blood pressure below 80 mm Hg (6 cases). With SECP therapy, 17 patients improved: The limbs became warmer, the heart rate decreased, and the pallor and cyanosis disappeared. In 5 of 6 patients, the systolic blood pressure increased to ~100 mm Hg. One patient did not respond to the SECP therapy.

ECG changes

Two reinfarction cases within the group of 52 patients studied were not analyzed for lack of typical acute stage changes of the ST-T segment. Of the other 50 patients, 31 (62%) showed remarkable improvement in their ECG after the first counterpulsation (1–3 h). The changes in the ECG were as follows: (a) Thirty-nine patients showed elevation of the ST segment before treatment. The elevated ST segment returned toward baseline after counterpulsation in 28 (64%). (b) Of the seven patients with inferior wall infarction with reciprocal depression of $ST_{V_4-V_6}$ before counterpulsation, the depressed ST returned to normal in six cases. (c) In seven patients with peaked T-wave, all returned to normal within 1 h after the start of SECP treatment. (d) The T-waves of 26 patients in this group changed from invert to upright 3–7 days after the start of treatment, reinverted within 9–14 days, and then followed the general trend of ECG changes associated with AMI.

Figure 1 shows the changes in the ECG of a patient with anteroseptal AMI after SECP therapy. This phenomenon of transient changes in the T-wave is not common in AMI patients. If this general viewpoint that the inverted T-wave during the acute stage of AMI signifies ischemia of the myocardium is accepted, then this upright T-wave may be the result of improvements in the myocardial blood perfusion. Nevertheless, its real significance and mechanism are subjects for further study.

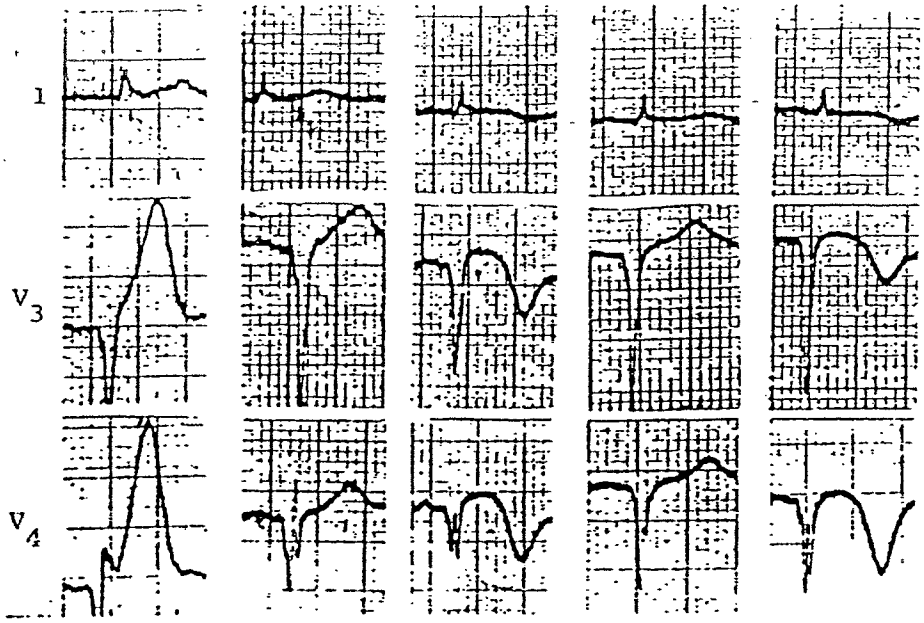


FIG. 1. Changes in the electrocardiogram of a patient with anteroseptal acute myocardial infarction after sequenced external counterpulsation treatment.

Laboratory data

Blood samples from 48 patients were obtained and analyzed for serum glutamic-oxaloacetic transaminase (SGOT) level, erythrocyte sedimentation rate (ESR), and leukocytes. The SGOT was elevated in all cases. In 15 patients, it returned to normal within 2 weeks, and in 15 it was normal at 20 days. The ESR was above normal in 42 of 44 patients, and in 22 of them it returned to normal in 2 weeks. Thirty-four of 52 patients had leukocytosis, and in 24 of them the leukocyte count returned to normal within 1 week. The laboratory data did not show any significant differences in these parameters between the SECP-treated group and the control group of 101 patients treated during the same period.

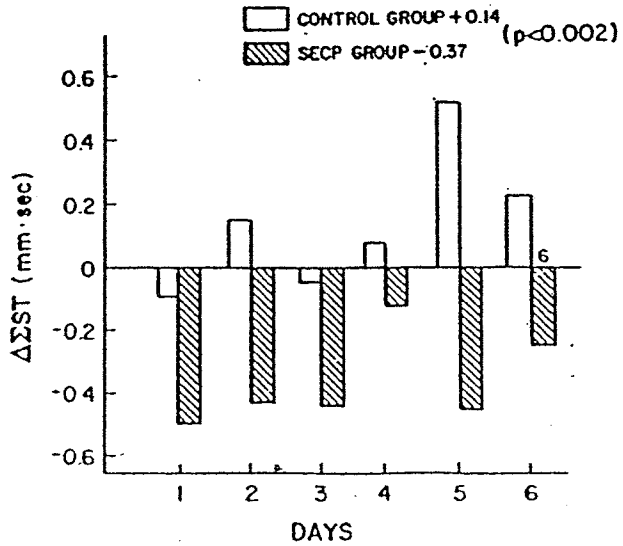


FIG. 2. Comparison of the changes in ΔΣST between the sequenced external counterpulsation (SECP)-treated group and the control group.

Complications

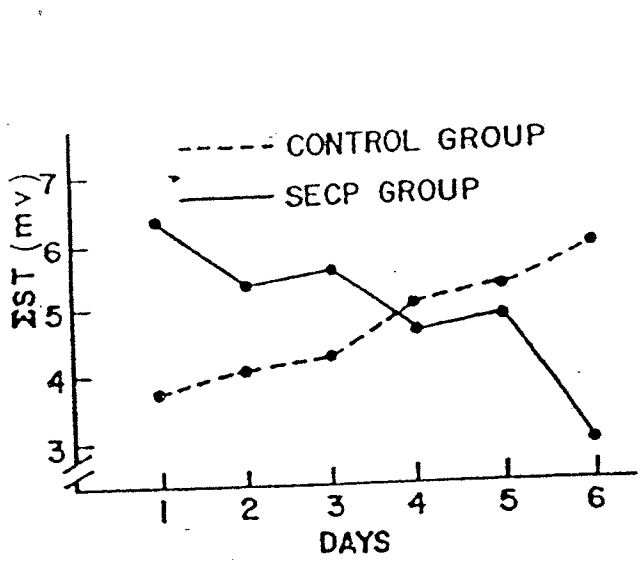
Seventeen patients had complications of severe arrhythmia before the start of SECP. Included in this group were one case of sinus tachycardia, nine cases of frequent premature ventricular beats (PVB), six cases of frequent premature atrial beats (PAB), and one case of atrial fibrillation (AF). In one case of PVB and in one case of PAB, the arrhythmia disappeared within the first hour of SECP. PVB and AF in two different patients persisted during the complete hospitalization and did not respond to SECP treatment. The arrhythmia of the remaining 13 patients disappeared within 6 h to 3 days after the start of SECP. It is difficult to evaluate whether or not this was due to the effects of SECP. Three cases were complicated with papillary muscle dysfunction. One patient had no apparent change in murmur during SECP therapy; the condition stabilized and the murmur reduced in intensity after 3 weeks. The murmur of another patient disappeared at the end of the first hour of treatment. The condition of the third patient improved after the first SECP, but the patient died of papillary muscle rupture the following day.

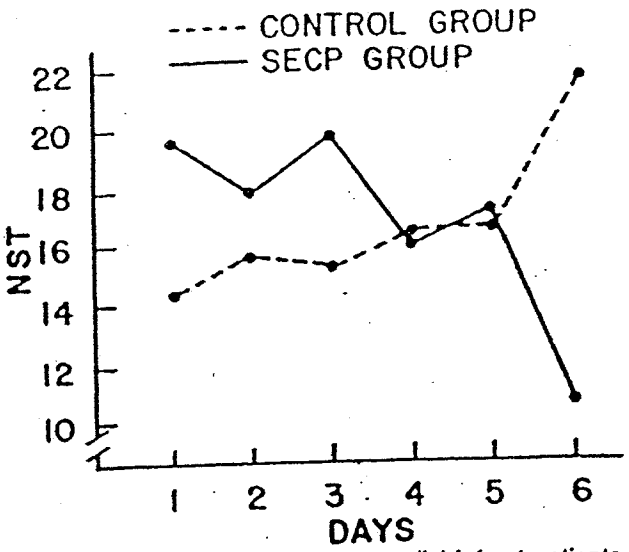
AMI was further complicated by other diseases such as cardiogenic shock (two cases), right heart failure (one case), pericarditis (three cases), pleurisy (one case), and pneumonia (four cases). SECP treatment did not create these complications.

Three of 52 patients died during hospitalization. The mortality rate was 5.8%. The causes of death were listed as papillary muscle rupture, ventricular fibrillation, and ventricular tachycardia.

Precordial ST segment elevation mapping

The changes in ΣST and NST that occurred daily





FIGS. 3 (left) and 4 (right). Effects of sequenced external counterpulsation (SECP) on acute myocardial infarct patients as measured by Maroko's ST elevation-mapping method. ΣST (Fig. 3) and NST (Fig. 4), indicators of infarct size, increased in the control group of eight cases. In all seven SECP cases, ΣST and NST decreased, indicating the beneficial effects of SECP in containing infarct size.

for the initial 6 days of treatment are shown in Fig. 2 and 3. It is obvious that both the ΣST and NST of the SECP group showed a downward trend, whereas those of the control group progressively increased. ΔΣST values of the SECP group from the first to the sixth day were as follows: −0.51, −0.41, −0.43, −0.13, −0.46, and −0.25 mV; with a total mean value of −0.37 mV. The mean values for the control group were as follows: −0.10, +0.15, −0.04, +0.10, +0.51, and +0.22 mV, with a total mean value of +0.14 mV. The differences between the groups were statistically significant ($p < 0.02$) (Fig. 4).

Hemodynamic changes

Improved hemodynamics were obtained in four of five patients with left heart failure. Both the CVP (Fig. 5) and the CI (Fig. 6) increased. PWP, used as an approximation of left ventricular filling pressure and preload, decreased and/or was maintained at clinically acceptable levels (Fig. 7). The symptoms of pulmonary congestion were improved. The typical changes for one patient are shown in Fig. 8. In one patient, sufficiently high diastolic augmentation was not obtained and the hemodynamic parameters did not improve. The PWP increased from 18 to 21 mm Hg, and SECP treatment was discontinued.

PTF-V_1 was calculated from 103 pairs of ECG recordings from 34 SECP-treated patients. The mean value of PTF-V_1 before SECP was −0.01 ± 0.011 mm-s and after SECP −0.007 ± 0.008 mm-s. The maximal fall was 0.031 mm-s. Figure 9 shows the variations in PTF-V_1 before and after SECP. In [illegible] of PTF-V_1 measurements, the negpatients who were in critical condition (Killip's pump failure class III) and had more negative values of PTF-V_1 became normal and/or improved after SECP. Twenty-three of 103 pairs of measurements remained unchanged. Nineteen pairs of measurements were more negative after SECP, and 18 of these still remained within normal limits. In one case, the PTF-V_1 became more negative than −0.03 mm-s after SECP, but the cardiac function remained stable.

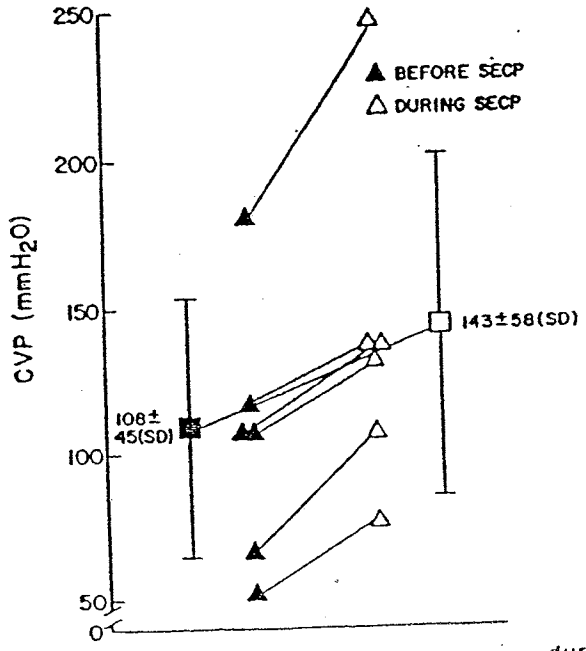


FIG. 5. Central venous pressure (CVP) changes during sequenced external counterpulsation (SECP) treatment

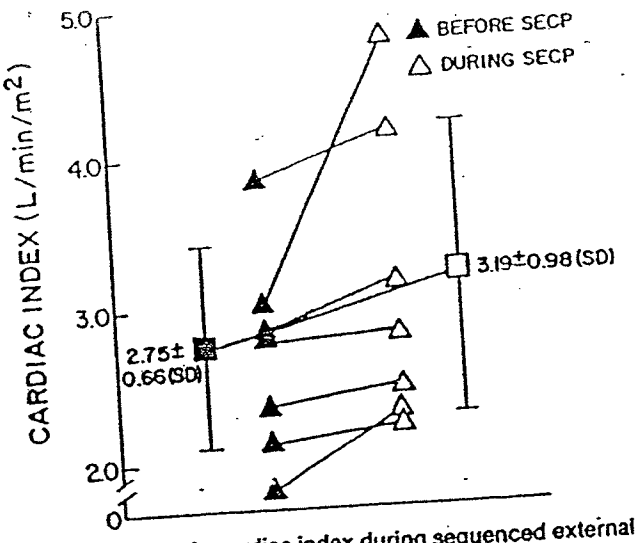


FIG. 6. Changes in cardiac index during sequenced external counterpulsation (SECP) treatment (n = 7).

DISCUSSION

The effectiveness of the general forms of ECP remains a subject of controversy.

Current available data have shown that most of the different effects reported by various groups using ECP are closely related to raising the level of diastolic augmentation (DA). The clinical effects reported by Solignac et al. (5), Loeb et al. (6), Khan et al. (7), and others were unsatisfactory because the DA was raised by only 32, 28, and 26%, respectively. The results from Soroff et al. (8), Ruiz et al. (9), Mueller et al. (10), and others were satisfactory, with the DA raised in the range of 59–104%. Table 2 lists the results and categorizes them

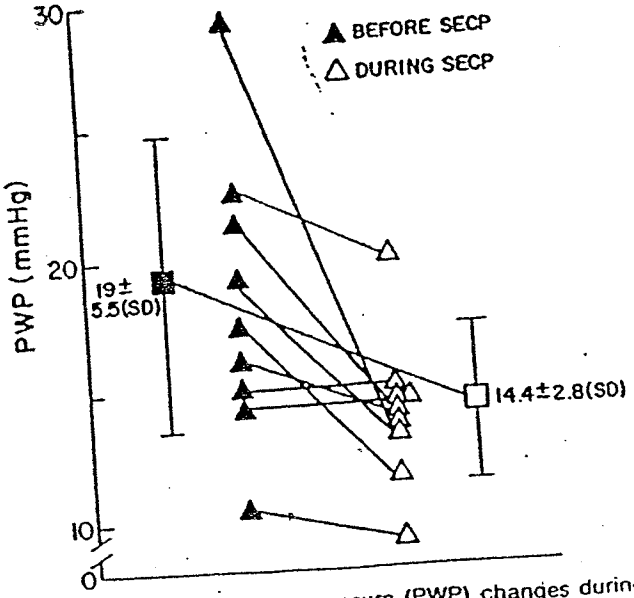


FIG. 7. Pulmonary wedge pressure (PWP) changes during sequenced external counterpulsation (SECP) treatment (n = 9).

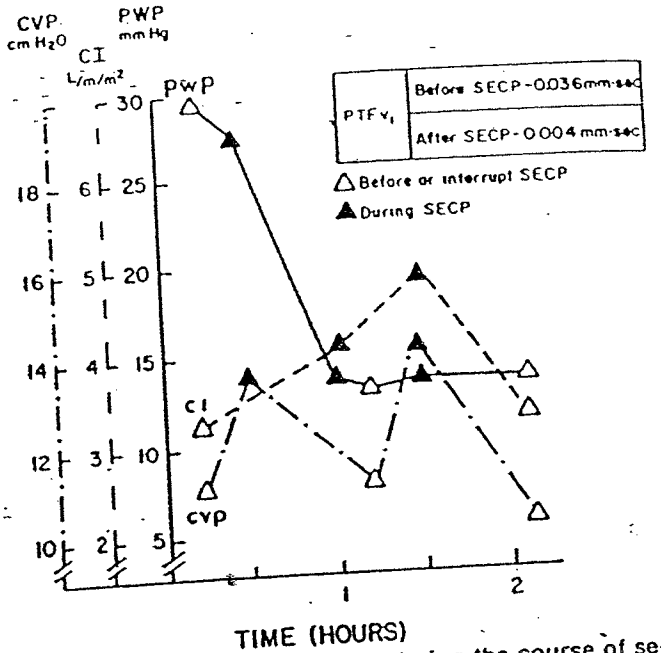


FIG. 8. Hemodynamic changes during the course of sequenced external counterpulsation (SECP) treatment of an acute myocardial infarct case complicated with left ventricular failure. CVP, central venous pressure; CI, cardiac index; PWP, pulmonary wedge pressure; PTF-V_1, P-wave terminal force of V_1.

into effective and noneffective counterpulsation groups. From the analyses of these data, it is assumed that effective counterpulsation is dependent on raising the DA to substantially high levels. Our experience using the four-limb SECP with buttock balloons has shown that the DA usually can be raised to twice the amplitude of the systolic wave (plethysmogram).

Using this SECP device, 52 AMI patients were treated. Rapid relief from severe chest pain was seen in 96.6% of the cases, whereas 62% showed the alleviation of the ischemic changes in ST-T. The long-term symptomatic relief from chest pain corresponds to the decrease in ST elevation and decrease in ΣST and NST. The reductions in these indicators demonstrate the distinct advantage of SECP in minimizing ischemic damage and infarct size. The hemodynamic data obtained from four of five cases of AMI with left ventricular heart failure showed a definite improvement in cardiac function. This finding indicates that SECP treatment is effective in salvaging myocardial ischemia. Further proof of the effectiveness of SECP treatment has been confirmed by the results in 108 patients with AMI reported from five clinics in China. Of these patients, 85.2% experienced relief from chest pain, and the improvement in the ECG was 62.5% (11).

One possible mechanism for preserving the myocardium during AMI is through the formation of

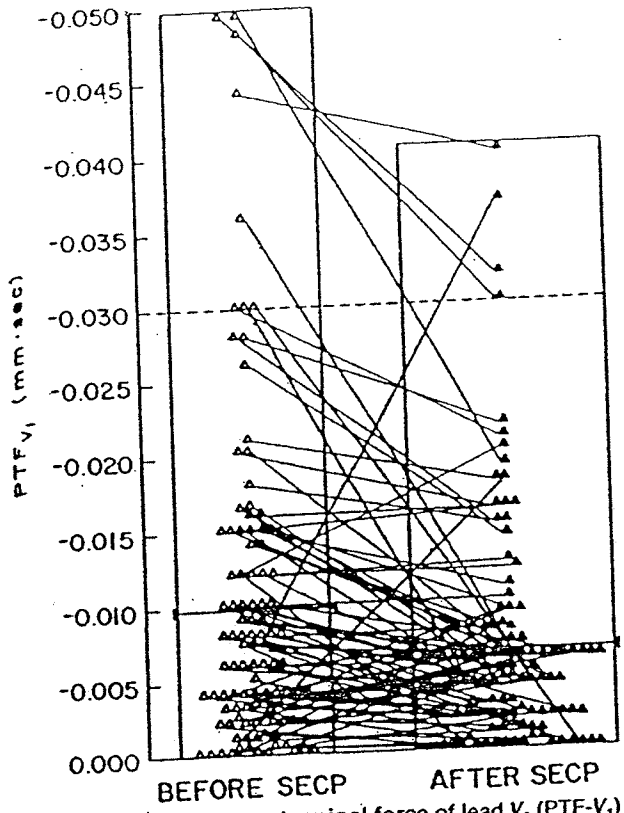


FIG. 9. Changes of P-wave terminal force of lead V_1 (PTF-V_1) before and after sequenced external counterpulsation (SECP) treatment.

collateral vessels. During AMI, low arterial pressures are evident in the obstructed blood vessels. With SECP, the coronary perfusion pressure is increased, and a pressure gradient between the obstructed blood vessels and the surrounding area also increases. As blood moves through the small vessels in response to this gradient, collateral vessels are formed. Therefore, with the higher coronary perfusion pressure, there is an increase in the number and the diameter of collateral vessels, resulting in a higher blood flow to the ischemic area.

This SECP device milks more blood from the four limbs to augment the pressure gradient between the ischemic area and the surrounding normal blood vessels. The addition of buttock balloons to the SECP system applies pressure on the muscular buttocks and the surrounding lower abdomen. Patients remain comfortable with a protector placed over the abdomen while adequate pressure is applied to the lower abdomen and the iliac artery. This design directs the blood toward the aorta, increasing both the DA and the coronary perfusion. These changes in the DA were observed with 16 healthy volunteers and 16 selected patients with coronary heart disease. Earlobe plethysmograms were used to assess the hemodynamic effects. Plethysmogram amplitude (S and D) and area under the curve (SP and DP) were measured, and the ratios between diastole and systole (D/S and DP/SP) were calculated and compared. With four-limb SECP and buttock balloons, the ratios of D/S and DP/SP increased to 1.91 ± 0.5 and 3.15 ± 1.68, respectively. The addition of buttock balloons increased the DA to 43.9% higher than that with four-limb SECP alone. The DA obtained with and without the use of buttock balloons is shown in Fig. 10.

Two main aspects, oxygen supply and consumption, are relevant and must be balanced for effective SECP treatment. During counterpulsation, coronary perfusion increases to provide the oxygen supply. At the same time, SECP applies pressure on both the arterial and venous systems. The return blood flow to the heart increases, augmenting the preload and the oxygen consumption. The coronary perfusion must satisfy the oxygen demands and result in a positive balance for both oxygen demand and consumption. Patients undergoing SECP exhibit this positive balance by the symptomatic relief of chest pain, alleviation of ST-T ischemic changes, improved ΣST and NST, and improved cardiac function.

In one of five AMI patients with left heart failure, the DA was not sufficiently raised with SECP treatment, resulting in a negative balance. The DA in this case was equal only to the level of the systolic wave. Perhaps in such a patient there is an aggravation of the preload without sufficient improvement in the myocardial blood supply. This confirms the authors' belief that increased DA is absolutely essential for effectual SECP. Five to 10% of the patient population may experience similar DA, equal to or lower than the level of the systolic wave.

To eliminate the increasing preload during SECP, the authors' suggestion for patients with critical left ventricular failure would be the combination of a vasodilator, such as nitroprusside, with SECP to correct the oxygen imbalance. Nitroprusside can produce a decrease in left ventricular filling pressure while increasing the cardiac output and reducing myocardial oxygen demands. A potential drawback to the use of a vasodilator appears to be the reduction in diastolic perfusion pressure, which might reduce coronary blood flow. The simultaneous application of SECP and nitroprusside to maintain diastolic perfusion pressure is a reasonable concept.

The precise hemodynamic and metabolic determinants for enhancing the DA remain to be identified, and the mechanisms of their action remain to be resolved in future work.

TABLE 2. *Levels of diastolic augmentation reported by various investigators*

Investigator	Subject of study	Diastolic augmentation (%)
Effective group		
Soroff et al. (8)	AMI and shock	104
Ruiz et al. (9)	AMI	100
Mueller et al. (10)	AMI	79
Al-Sadir et al. (12)	AMI	78
Ruiz et al. (9)	Normal person	70
Banas et al. (13)	Angina	66.4
Lamberti et al. (14)	AMI	61.4
Clapp et al. (15)	Angina	59
Kataoka et al. (16)	AMI model (dog)	32.9
Ruiz et al. (9)	AMI model (dog)	30.5
Ryan et al. (17)	Angina	18 mm Hg[a]
Watson et al. (18)	AMI model (dog)	30 mm Hg[b]
Noneffective or unsatisfactory group		
Solignac et al. (5)	Angina	32 (D = S)
Loeb et al. (6)	Angina	28.4
Khan et al. (7)	Coronary artery disease	26
Mueller (19)	AMI and shock	11 mm Hg[a]
Singh et al. (20)	AMI and shock	9 mm Hg[a]

Diastolic augmentation equals the increasing portion of diastolic pressure compared with the original diastolic pressure. AMI, acute myocardial infarction; D, amplitude of the diastolic wave; S, amplitude of the systolic wave.

[a] Increase of mean diastolic pressure.

[b] Increase of peak diastolic pressure.

CONCLUSION

For a majority of AMI patients, the application of SECP is an effective procedure for assisted circulation. SECP increases the coronary pressure and may salvage the ischemic myocardium that surrounds the necrotic center. It can be applied to a large population of patients for the treatment of ischemic heart disease, owing to its noninvasive character, its safety and simplicity, and the rapidity of treatment. However, there remain 5–10% of the population experiencing unsatisfactory levels of DA for whom the clinical effectiveness of SECP may be limited. Concerning the increasing preload occurring during counterpulsation, the authors' suggestion for the treatment of critical patients with left

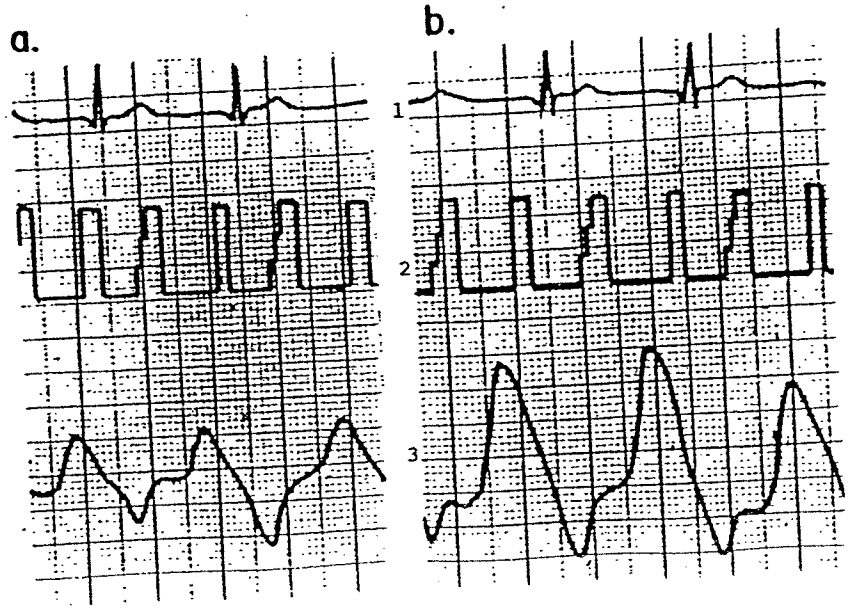


FIG. 10. Diastolic augmentation created by sequenced external counterpulsation without (a) and with (b) buttock balloons. The tracings from top to bottom include (1) the electrocardiogram of lead II, (2) the valve signal, and (3) the earlobe plethysmogram.

ventricular failure would be the use of a vasodilator such as nitroprusside in combination with SECP treatment.

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