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EVALUATING THE RESPONSE OF MILD HYPERTENSIVES TO BIOFEEDBACK-ASSISTED RELAXATION USING A MENTAL STRESS TEST

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Summary — The objective of this study was to evaluate the long term effect of a program of biofeedback-assisted relaxation on hypertensive patients by mental stress test reactivity. Twenty mild hypertensive patients were subjected to a mental arithmetic stress test before and six months after completing biofeedback-assisted relaxation therapy. The therapy consisted of 10 sessions of biofeedback-assisted relaxation instruction and continuous home practise. The study group was compared to a control group. The biofeedback-assisted relaxation treatment produced a mild improvement in blood pressure control and decreased the dose of drugs used as well as a decrease in state-anxiety ($p<0.05$). The stress-induced increases in systolic blood pressure, diastolic blood pressure, heart rate, galvanic skin response and skin temperature were all significantly attenuated six months after completion of biofeedback-assisted relaxation treatment. Copyright © 1996 Elsevier Science Ltd

Non-pharmacological treatment is widely accepted either as an adjunct or as the sole intervention for essential hypertension (Silverberg, 1990). Stress management or relaxation therapy is still a controversial method of non-pharmacological treatment (National Institute of Health, 1992) although it has been known for a considerable time that relaxation of skeletal muscles can lower blood pressure (Kaplan, 1991). Most of the currently popular relaxation therapies have shown some beneficial effect of blood pressure reduction, but long term clinical effectiveness was not confirmed (National Institute of Health, 1992; Kaplan, 1991; Jacob, Wing, & Shapiro, 1987).

In the last 20 years, several non-pharmacological methods aimed at modifying behavioral patterns have been introduced (Shapiro & Goldstein, 1982). Two have been adopted: a

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psychotherapeutic one aimed at relieving underlying stress and one aimed at controlling blood pressure by means of arousal reduction (Achmon, Granek, Golomb, & Hart, 1989). A number of studies have shown that patients are able to control their blood pressure using relaxation techniques (Achmon *et al.*, 1989; Health and Public Policy Committee, 1985; Blanchard, McCoy, Musso, Maryrose, & Gerardi, 1986) and, as a result, biofeedback-assisted relaxation treatment has been introduced as a means of managing mild hypertension (Health and Public Policy Committee, 1985; Blanchard *et al.*, 1986; Subcommittee of the Joint National Committee 1984, 1986; Jacob, Shapiro, O'Hara, Portser, Kruger, Gatsonis, & Ding, 1992). There are, however, several problems associated with this treatment: first, the effects, either short- or long-term, are difficult to assess (Health and Public Policy Committee, 1985; Wittrock & Blanchard, 1992; Blanchard, 1990) and second, the procedure is relatively expensive in that the services of a trained psychologist are required for individual instruction sessions lasting from 20 to 60 minutes. Finally, only about half of the subjects comply with the program and of those not all respond favorably.

Over several years, research has sought to identify psychological and physiological characteristics that can be used to predict which patients are most suitable for this mode of treatment (Blanchard, 1990; McGrady & Higgens, 1989). It was found that patients who responded best to this treatment were those displaying autonomic overreactivity manifested by, for example, cool hands, high heart rate or chronic effects of stress-high anxiety and high cortisone levels. Other studies (Cottier, Shapiro, & Julius, 1984) have reported that mild hypertensives with high resting sympathetic tone are the best candidates for a progressive muscle relaxation program. Relaxation has been reported to be more effective in patients with higher levels of blood pressure response to emotional stress, i.e., patients displaying some form of over-reactivity to stimuli (Aivazian & Zaitsev, 1991).

The exact mechanism by which relaxation therapy lowers blood pressure remains elusive. (Patel & Marmot, 1987) A number of studies have shown that compared to normotensives, hypertensives are hyperreactive across stimuli, emotional and physical (Paran, Neumann, & Cristal, 1992; Falkner, Onesti, Angelakos, Fernandes, & Langman, 1979; Hollenberg, Williams, & Adams, 1981; Larkin, Zayfert, Abel, & Veltum, 1992). Biofeedback training has been shown to reduce this excessive reactivity (Jorgensen, Houston, & Zurawski, 1981; Patel & North, 1975).

Recent research (Albrigh, Andreassi, & Brockwell, 1991) demonstrated that after a course of biofeedback instruction, reactivity to a psychological stressor (in the form of an oral quiz) was significantly reduced. This led these workers to postulate a reduction in sympathetic nervous system activity as the possible mechanism for these changes.

The aim of the present study was to evaluate the long-term effect of a program of biofeedback-assisted relaxation on the reactivity of mild to moderate hypertensives to laboratory-induced psychological stress. In the course of our study, we sought answers to the following questions:

(1) Are there any characteristics to identify subjects who will adhere to a full course of biofeedback-assisted relaxation treatment?
(2) Do responders differ in their psychological and/or physiological profiles from non-responders and what is the relation, if any, between an overreaction to laboratory-induced mental stress and the response of a person to biofeedback-assisted relaxation treatment?
(3) What is the long term effect of biofeedback-assisted relaxation treatment?

Method

Subjects

Thirty-six mild hypertensive men and women (mean age 50.5, S.D. 8.7) attending the Hypertension Clinic of the Soroka Medical Center were randomly allocated for biofeedback-assisted relaxation treatment out of the referred patients to the clinic. Of the study population, 57% were male and 74% had received 12 or more years of education. As controls served a group of 12 patients, matched for age (mean 46.8, S.D. 9.6) and hypertension, who underwent the same protocol (with regard to the physiological parameters) with the exception of the biofeedback-assisted relaxation treatment. The control group was randomly allocated from the same general population of hypertensive patients who served as a pool for controls for several ongoing studies. From this pool we matched 12 patients. All patients, both study and control, signed an informed consent. The patients in the study group underwent baseline assessment for allocation to biofeedback-assisted relaxation. Patients with mild hypertension (140/95 to 160/100) without pharmacological treatment or on one drug only were included. Patients with any other disease or complication of hypertension, who were uncooperative or who had a history of any mental illness were excluded. Of the initial 36 patients, 20 completed the biofeedback-assisted relaxation program (Group I) and, after completion, underwent repeated assessment of their responses to a laboratory-induced mental stress. Sixteen patients (Group II) were assessed at baseline, but chose not to continue the treatment program. In Group I, 9 did not receive any drug treatment, and 5 received a calcium antagonist, 4 an ACE inhibitor and 2 a low dose of beta blocker. Mean readings at baseline were: systolic blood pressure 147.7 mmHg; diastolic blood pressure 94.0 mmHg for Group I, and systolic blood pressure 143.0 mmHg; diastolic blood pressure 92.9 mmHg for Group II. systolic blood pressure 148 mmHg; diastolic blood pressure 92 mmHg for the control group.

Procedure

The first session of the biofeedback-assisted relaxation program was attended by all 36 subjects and included demographic, medical and psychological evaluations, the latter by completing the following questionnaires:

(1) State-Trait Personality Inventory (STPI) adapted from Spielberger (1972) translated into Hebrew and validated by Zeidner and Ben-Zur (1989) The STPI includes 3 sub-scales assessing anger, curiosity and anxiety, each measured both as trait and as state.
(2) Beck Depression Inventory, BDI (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). This scale is a widely-used measure and has been applied to a variety of study populations.
(3) Cognitive Resources, SCS a measure referring to what people do when stressful circumstances call for self-direction. This scale has been validated with a number of study populations in Israel (Rosenbaum, 1990).

Psychological stress was induced by a mental arithmetic test. After 15 minutes of rest, the patient was required to perform a sequential subtraction of a two-digit number from a four-digit number for five minutes (Falkner *et al.*, 1979; Larkin *et al.*, 1992). Both before and at minute intervals during the mental stress test and three times during a period of post-test relaxation (10 minutes), blood pressure and heart rate were measured. Galvanic skin response (GSR) and skin temperature were monitored continuously and recorded at minute intervals. Blood pressure and

heart rate were measured by a Dynamap automatic blood pressure device. Atlas Physiological Processor was used to assess the other physiological parameters.

The treatment protocol consisted of patients meeting with a trained psychologist individually at weekly intervals over a 10-week period (each session lasted 40-50 minutes). The patients were taught relaxation techniques: muscle relaxation according to Jacobson (Bernstein & Borkovec, 1973), diaphragmatic breathing (Bacon & Poppen, 1985) and pleasant images (Turk, Meichenbaum, & Genest, 1983). They were required to practise at home. The biofeedback training was practised on GSR and skin temperature. For the duration of the treatment, blood pressure, heart rate and pharmacological treatment of the subjects were closely monitored by repeated measurements. In order to measure long term effects, the patients and controls were assessed once more by the identical psychological and mental stress tests, six months after the completion of treatment.

Statistical Analysis

Means, standard deviations and standard errors of each parameter were calculated, paired comparisons of mean values before and after biofeedback-assisted relaxation treatment were performed using the SPSS program. Student's *t*-tests were performed to compare between control and study group. Correlations between physiological and psychological measures were calculated.

Results

Initially we compared the subjects who completed the program (Group I), with those who chose not to continue the program (Group II). No significant differences could be detected at baseline or during stress in the physiologic parameters. On the psychological measures it was found that patients in Group I were significantly less depressed than those in Group II.

Table 1 shows the parameters for the group who completed the biofeedback training, before and after the intervention and those of the control group at the two points of evaluation. The table reveals that at the initial evaluation no difference could be found in baseline blood pressure, heart rate, GSR, and skin temperature values between the study and the control groups. Mental stress caused a significant change in all parameters in a similar way in both groups, i.e., the difference between baseline and max values was significant and similar in both group ($p<0.01$) at the first evaluation. However, the study group showed significantly higher reactivity to mental stress in systolic blood pressure (δ 28 vs. δ 12.8, $p<0.05$) at baseline. This difference was not significant at the second evaluation of both groups.

At the second evaluation, i.e., at follow-up, six months after the intervention in the study group, and the regular six month follow up for the control group, there was a significant difference between the two groups. The control group showed a reaction to the stress test similar to the first evaluation in all parameters. However, the study group showed a significant reduction to the response to mental stress after the biofeedback-assisted relaxation training in all five measures, systolic blood pressure, diastolic blood pressure and heart rate ($p<0.02$) and GSR and skin temperature ($p<0.01$).

The psychological assessments are shown in Table 2. It can be seen that only the state anxiety (ANX-State) decreased significantly ($p<0.05$), while no changes in other parameters were significant.

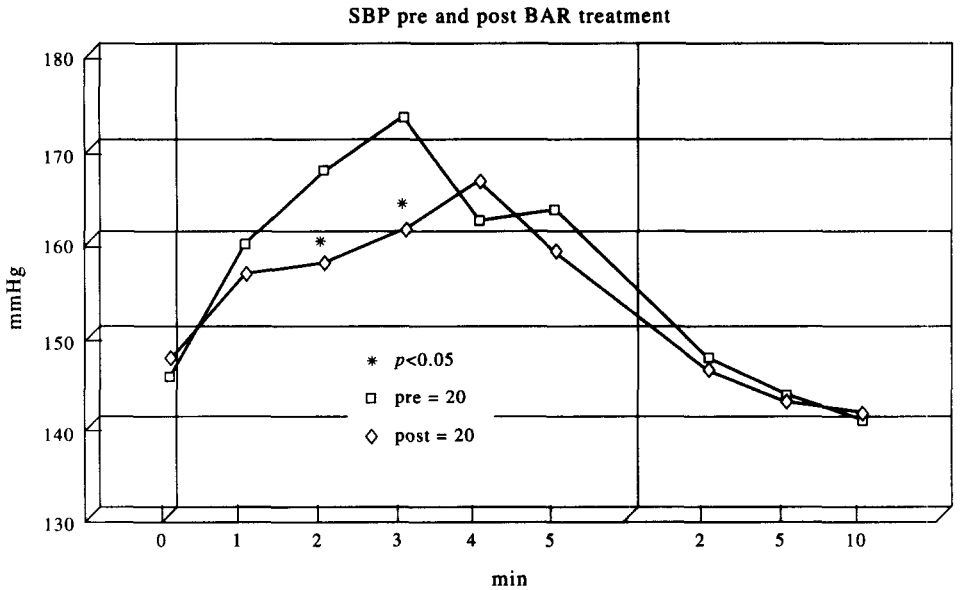

Figure 1. Systolic blood pressure during the mental stress test pre and post biofeedback-assisted relaxation treatment for study group.

Figures 1–5 illustrate some of these results graphically. Figure 1 shows the pattern of change in systolic blood pressure throughout the mental stress tests before and after the program; Figure 2, the changes in diastolic blood pressure; Figure 3, the changes in heart rate; Figure 4, those in GSR while Figure 5 shows the changes in skin temperature.

An additional criterion of 'success' in the study group regarding the treatment was based on the blood pressure values as measured in the clinic (i.e., not during the biofeedback session). As shown in Table 1, baseline blood pressure measurements in the posttreatment group were not different from the pretreatment values. However, the patients' blood pressure was measured weekly in the clinic and whenever the blood pressure decreased the dosage of the drug was lowered. The decrease in blood pressure and/or in the level of pharmacological therapy was assessed on a scale of 0-3 blindly by two of the investigators, with zero connoting an increase in blood pressure and/or level of medication, 1 no change, 2 a moderate decrease in blood pressure and/or level of medication and 3, a pronounced improvement in both. Inter-rater reliability was .89 as measured between two independent judges. The resulting score of each subject was used as a 'blood pressure success' criterion and was correlated with each of the physiological and psychological parameters both before and after the program. Of the 20 patients, 9 had a score of 2 and 11 a score of 3 (mean 2.55, S.D. 0.51). No significant correlation was found between these scores and the psychological measures. However, among the physiological parameters, skin temperature at baseline and post mental stress were each negatively correlated with the 'blood pressure success' criterion ($p<0.05$ in each case) showing that patients with an initially higher level of stress, as shown by a lower peripheral temperature, responded better to biofeedback-assisted relaxation. GSR at post mental stress stimulation before the program correlated positively with the 'blood pressure success' criterion ($r=0.46$) meaning that patients who achieved deeper relaxation after the mental stimuli (as measured by GSR) benefited more from the program.

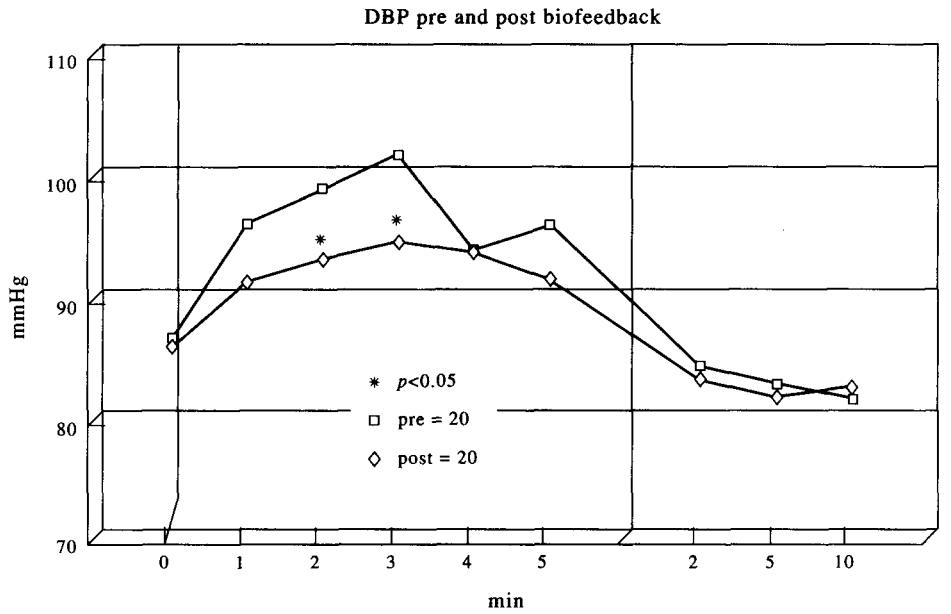

Figure 2. Diastolic blood pressure during the mental stress test pre and post biofeedback-assisted relaxation treatment for study group.

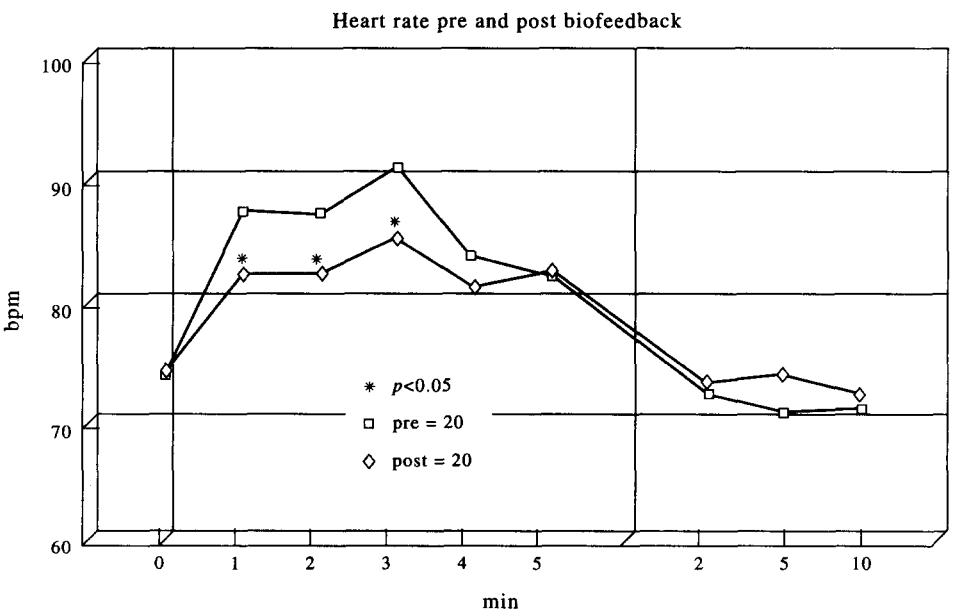

Figure 3. Heart rate during the mental stress test, pre and post biofeedback-assisted relaxation treatment for study group.

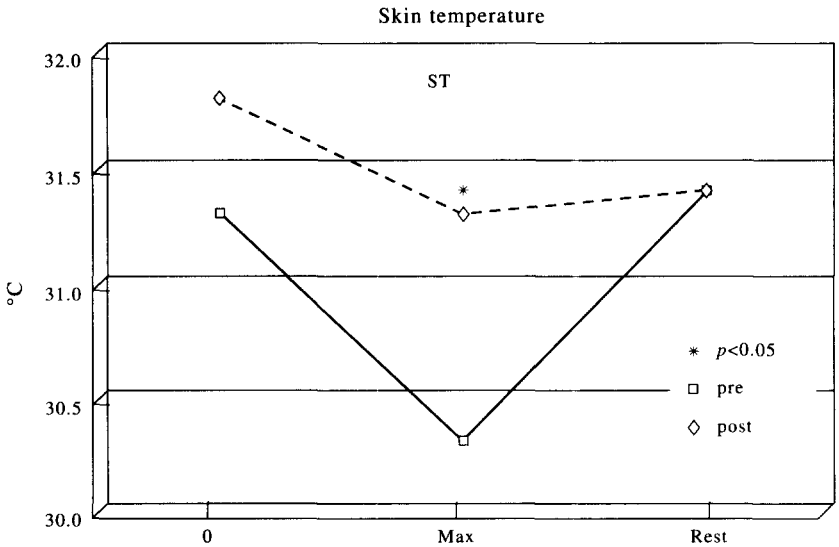

Figure 4. Skin temperature during the mental stress test, pre and post biofeedback-assisted relaxation treatment for study group.

Discussion

Biofeedback-assisted relaxation has become one of the widely used non-pharmacological methods of treatment of essential hypertension. However, it has become evident that not all patients respond favorably to (biofeedback-assisted relaxation) treatment which makes its cost-

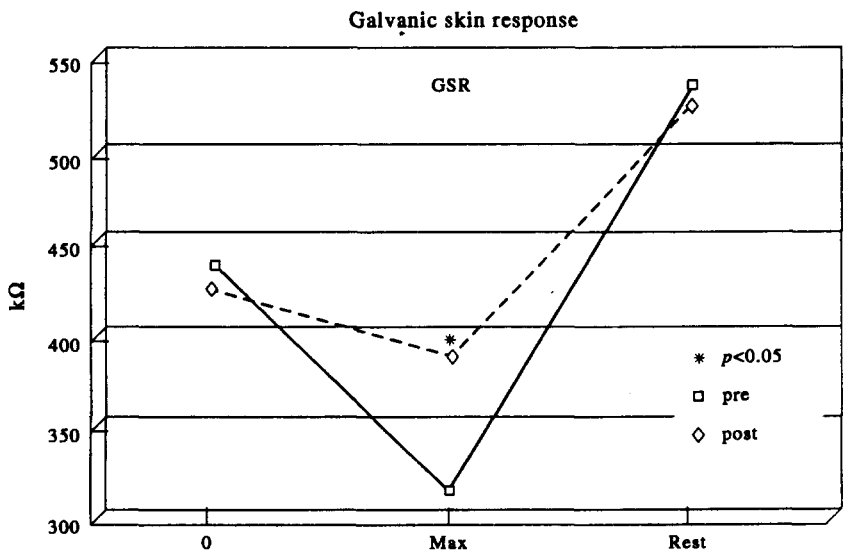

Figure 5. Galvanic skin response during the mental stress test, pre and post biofeedback-assisted relaxation treatment for study group.

Table 1

Pre- and Post-Program Measures During Mental Stress Test for Study and Control Group

Study group (n=20)				Control group (n=12)		
	Baseline	Max.	δ^a	Baseline	Max.	δ^a
I. Pre-treatment						
Systolic blood pressure mmHg	145.1	173	28^+	147.2	160	12.8
Diastolic blood pressure mmHg	86.6	101.5	14.9	94.6	109	14.4
Heart rate bpm	73.4	90.8	17.5	72	86	14
GSR .Ω	438.5	314.9	$28.2\%^b$	492.7	325.2	$34\%^b$
Skin temperature °C	31.3	30.3	$3.2\%^b$	32.0	30.8	$3.8\%^b$
II. Post-treatment (follow-up)						
Systolic blood pressure mmHg	146.1	165.9	19.0^{**}	145.6	158.2	12.6
Diastolic blood pressure mmHg	85.8	94.4	8.6^{**}	95.5	109.6	14.1
Heart rate bpm	73.8	84.9	11.1^{**}	70	93	23
GSR Ω	424.6	388.1	$8.6\%^{b*}$	521.6	356.4	$31.7\%^b$
Skin temperature °C	31.8	31.3	$1.6\%^{b*}$	31.6	30.4	$3.8\%^b$

Key: ^{a} δ values are differences between maximum and baseline; % ^{b} are δ values expressed as a percentage of the baseline value; $^*p<0.01$; $^{**}p<0.02$ comparing δ pre- and post-biofeedback-assisted relaxation treatment; $^+p<0.05$ comparing δ study group to δ control group at baseline all the differences from baseline to max were significant $p<0.01$; Standard deviation available upon request.

effectiveness questionable. An ability to predict which patients will respond most successfully to biofeedback-assisted relaxation treatment could improve efficacy. Therefore, we tried in our study to characterize our patients with using psychological and mental stress responsiveness as predictors of adherence and success in this treatment.

When comparing those who underwent the treatment program and those who did not, the

Table 2

Psychological Parameters of Treatment Group Before and After Biofeedback-assisted Relaxation Training During Mental Stress

	Before biofeedback-assisted relaxation training		After biofeedback-assisted relaxation training	
	Mean	S.D.	Mean	S.D.
BDI	5.8	3.6	5.2	3.4
SCS	32.9	21.9	34.4	18.1
STPI	127.5	15.3	123.3	12.8
ANX-State*	19.6	6.8	16.9	5.3
ANG-State	11.0	1.9	11.5	2.5
CUR-state	30.4	5.1	29.2	3.7
ANX-Trait	18.4	3.6	17.0	2.9
ANG-Trait	18.5	4.7	17.6	4.9
CUR-Trait	29.7	4.6	31.0	3.6

* $p<0.05$.

only significant difference was that the latter had significantly higher depression scores. Other studies have found similar rates of patients not accepting biofeedback treatment (Health and Public Policy Committee, 1985; Glasgow, Gaarder, & Engel, 1982; Kaplan, 1985). This suggests that patients who choose not to participate in biofeedback-assisted relaxation treatment do so because they are depressed in some degree.

The biofeedback-assisted relaxation treatment resulted in a positive change regarding blood pressure which, in our study, was expressed as a reduction in the level of drug treatment in a majority of patients ('success' score). This result is in keeping with previous studies (Jacob *et al.*, 1992; Blanchard, 1990).

As to the prediction of 'success' in the program, i.e., the decrease in blood pressure and/or lowering the amount of medication, none of the psychological measures used here were found capable of predicting a decrease in blood pressure in biofeedback-assisted relaxation treatment.

Among the physiological measures, GSR and skin temperature at baseline and post stress relaxation were significantly correlated with 'success'. The colder the subject's hands were before the test, i.e., the higher his basic anxiety level, the more he benefited from the program; the more the GSR increased post-test, i.e., the better the subject's spontaneous relaxation after the mental stress, the better he succeeded in lowering his blood pressure throughout the program. These results are in accordance with previous studies (McGrady & Higgens, 1989; McGrady, Utz, Woerner, Bernal, & Higgens, 1986) where it was found that individuals most likely to lower their blood pressure by relaxation techniques are those manifesting evidence of higher stress response.

Although we used the measure of 'success' in the evaluation, our main assessment was made by means of a mental stress test. Evaluation of mild hypertensives before and after treatment is usually made by routine 'office' blood pressure measurement. It is well documented (Siegel, Blumenthal, & Divine, 1990) that this measure fluctuates with influences related both to patients and to physicians. It is possible that some of the conflicting results in the biofeedback literature (National Institute of Health, 1992; Subcommittee of the Joint National Committee 1984, 1986) are attributable to low reliability of the assessment measure. Moreover, in a recent study Jamner, Shapiro, Hui, Oakley, and Lovett (1993) have shown that certain personality traits (hostility) correlate to the blood pressure results in different methods of measurement. High hostility patients were shown to have consistently higher blood pressure regardless of the method of measurement while low hostility patients tend to be more variable and their diagnosis of hypertension depends more on the method of measurement. This finding shows the desirability of choosing more than one method of blood pressure measurement, especially for the stress related 'white coat' hypertensives.

Paran, Neumann, Cristal, and Lowenthal (1991), in an earlier study demonstrated the value of a mental stress test for evaluating pharmacological treatment in mild hypertensives. In this study it was shown that repeated application of the mental stress test did not attenuate the individual response to the test or the repeated group mean comparisons. The same result was seen in the present study as the control group showed no diminished response to the mental stress test throughout the follow-up period. In contrast, the study group showed changes in all the physiological parameters examined. The study group showed higher initial responsiveness to the mental stress test than the control group. It is likely that patients responding to biofeedback-assisted relaxation treatment are those who have higher stress levels initially. This was not revealed by the psychological measurement but was shown by the mental stress test, which later demonstrated the positive effect of biofeedback-assisted relaxation. The lowered physiological and psychological situational reactivity demonstrates the benefit of this program,

in accordance with results obtained in earlier studies (Shapiro & Goldstein, 1982; Aivazian & Zaitsev, 1991; Jorgensen *et al.*, 1981; Patel & North, 1975).

Since the second post-treatment evaluation was performed six months after the subject completed the program, these results represent a medium to long-term effect of this intervention (see Blanchard, 1990).

Twenty-four hour ambulatory blood pressure monitoring has been introduced recently as a more reliable means of evaluating blood pressure (Wittrock & Blanchard, 1992). In a second phase of the present study, now in progress, we are using this method.

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