Behavioral and Physiological Effects of a Beta Blocker and Relaxation Therapy on Mild Hypertensives

C. A. ADSETT, MD, A. BELLISSIMO, PHD, A. MITCHELL, RN, MSC,
N. WILCZYNSKI, BA, AND R.B. HAYNES, MD, PHD

In this industrial-based study we compared the blood pressure (BP)-lowering effectiveness of relaxation, a beta blocker, and the combined use of these two treatments in 47 untreated, mildly hypertensive blue collar steel workers. Using a randomized two by two factorial design, patients received either nadolol or placebo drug daily, and either a relaxation training or an education program, each lasting 8 weeks. A pre-intervention and post-intervention stress test measured response of heart rate and BP to mental and physical tasks. BP assessments were done at baseline, post-intervention, 1 month, and 3 month follow-up. Change in several self-report measures was determined. Results showed that beta blocker was more effective in lowering BP than placebo, but relaxation was not more effective in lowering BP than health education. The combined effect of beta blocker and relaxation was not superior to beta blocker alone. Compliance with relaxation practice was not superior to compliance with medication. We conclude that pharmacologic treatment is superior to the relaxation therapy tested.

INTRODUCTION

Despite the proven benefit of pharmacologic treatment, about 30% of hypertensive patients who remain under medical care fail to take enough medication to achieve therapeutic benefit (1). Providing their effectiveness is established, nonpharmacologic interventions, such as stress management, might be more acceptable strategies for treatment of hypertension.

The effectiveness of stress management in lowering blood pressure (BP) is supported by some studies (2–8), but its clinical usefulness is questioned by others (9–12). Few studies actually compare stress management techniques with antihypertensive drug treatments for potency and even fewer for acceptability (13–16). In spite of the hope that stress management, due to its lack of adverse effects and the feelings of well being that may accompany it, might produce better treatment compliance than medication in hypertensive patients, almost no studies specifically examine this issue. The comparison by Luborsky et al. (13) of drug and behavioral treatments seems to be the only study which examines compliance with the two treatments. That study showed a significantly lower compliance with relaxation than with medication. One of the purposes of our worksite study was to compare compliance as well as treatment efficacy for relaxation therapy and medication in hypertensive patients.

The primary aim of this randomized two by two factorial experiment was to compare the effectiveness of relaxation

From the Department of Psychiatry (C.A.A., A.B.), School of Nursing (A.M.), Department of Clinical Epidemiology and Biostatistics (A.M., N.W., R.B.H.), and Department of Medicine (R.B.H.), Faculty of Health Sciences, McMaster University, Hamilton, Ontario, Canada.

Address reprint requests to: C. A. Adsett, M.D., Department of Psychiatry, Faculty of Health Sciences, McMaster University, 1200 Main Street West, Hamilton, Ontario, L8N 3Z5.

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and medication therapy separately and in combination in the treatment of mild hypertension. We also compared the ability of these treatment regimens to reduce the effect of physical and psychological stressors on the cardiovascular system. The study included measures to determine whether relaxation therapy and beta blocker medication would reduce an individual's Type A behaviors (e.g., overly driving, competitive, impatient) and alter his perception of daily stresses in his life. These factors have been identified by a number of researchers as risk factors for heart disease (17). Also assessed was the effect of the study treatments on reducing anxiety and anger, two affects theorized to be associated with increased cardiovascular disorder (18). The majority of study participants were blue collar workers (89%) employed in a local steel mill. To date, worksite-based studies of stress management techniques have utilized white collar or skilled workers only (8–10).

METHODS

Participants

Male, mildly hypertensive employees of Dominion Foundries and Steel Company Limited (DOFASCO) of Hamilton, Canada, were recruited for study participation and included: a) patients who were initially treated and controlled on medication and returned to a hypertensive level after drug withdrawal as part of another study; and b) untreated mild hypertensives identified through medical chart audits at DOFASCO. DOFASCO is a progressive steel mill in which the workers share in profits, are not unionized, have never gone out on strike, and experience very few lay-offs.

Participants met the following eligibility criteria: average untreated diastolic blood pressure (DBP) between 90 and 105 mm Hg; age between 30 and 65; no contraindication to nadolol; no evidence of target organ disease such as prior myocardial infarction, congestive heart failure, stroke/transient ischemic attack, renal damage, intermittent claudication, or angina pectoris; no history of a psychotic disorder, diabetes, asthma, chronic obstructive lung disease, or alcoholism; and fluent in English. Eligibility of employees was assessed through medical chart information at DOFASCO, participant interviews, and information from the employee's family physician.

Procedure

A flow chart (Fig. 1) presents an overview of assessments and interventions.

Using a computer-generated series of random

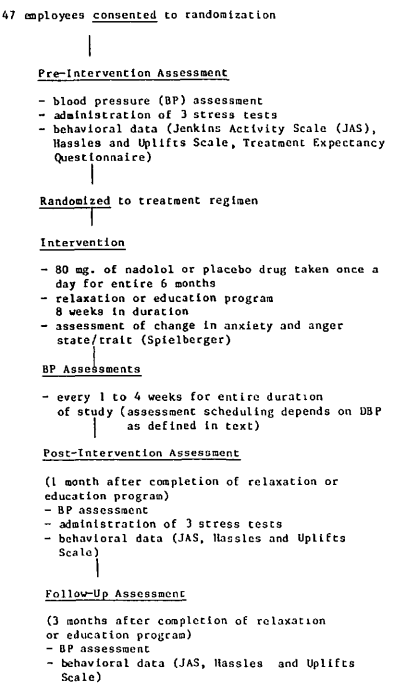

Fig. 1. Flow chart of assessments and interventions.

numbers and a blocking pattern of 4, eligible participants were randomly allocated sequentially to one of four treatment groups: a) placebo medication and relaxation therapy; b) beta blocker and relaxation therapy; c) placebo and education (placebo for relaxation); or d) beta blocker and education. Subjects were stratified by two variables: 1) untreated eligibility DBP (90–95 mm Hg, 96–105 mm Hg), and (2) previous hypertensive treatment status (treated, untreated). The participants were "blind" to the treatment group. This was achieved by advising the participants that they would receive an active or inactive medication, and that they would participate in stress management program #1 or #2. Participants were seen at DOFASCO's Medical Department.

Treatments

Drug treatment and compliance. The participant received either an inactive medication or 80 mg of beta blocker (nadolol) once a day. The tablets were similar in appearance, packaged identically, and administered in a double blind fashion.

In order to assess medication compliance, subjects were questioned about medication adherence at BP assessments and were reminded to take the pills daily. In addition, subjects were asked to consent to a home visit. The ostensible purpose of the visit was to assess BP away from the work environment. At the home visit three BP readings were taken. The subject was then asked to produce the study medication, which was counted. Compliance was calculated by dividing the number of pills missing from all containers by the number of pills which should have been missing.

Relaxation treatment and compliance. The relaxation and education programs each consisted of eight weekly 1-hour sessions. A total of four relaxation programs and four education programs, with four to eight participants each, were conducted by two therapists, one male and one female. The therapists were trained identically, and each conducted two relaxation and two education programs. The programs were similar with the exception that the subjects receiving the relaxation treatment were trained in doing progressive muscle relaxation monitoring daily relaxation practice, and using abbreviated relaxation strategies in stressful situations. Otherwise, both groups received the same information about hypertension, lifestyle, and stress (19, 20).

The training of relaxation and self-monitoring was systematic, progressively moving toward achieving the relaxation skill for daily application. The standard protocol used by the therapists to train the subjects in progressive muscle relaxation was based on the technique developed by Jacobsen (21), and the script that they used was similar to the one published by Ferguson et al. (22). During the first session, the relaxation portion was taped and each subject had a tape to take home for daily practice.

Each of the eight treatment sessions included the practice of relaxation. As the program progressed, the relaxation training included the use of scanning of muscles for tension and the use of brief relaxation (breathing, imagery) to reduce tension during the day.

During 5 weeks of the 8-week relaxation program participants were instructed to practice relaxation once a day and record their tension, duration, and severity rating (scale: 0, most relaxed; -10, most tense) before and after the relaxation exercise. During the remaining 3 weeks participants were asked to monitor the application of brief relaxation in handling daily stressful situations. The relaxation logs which were handed in weekly were used to assess compliance with the relaxation treatment. Following the eight treatment sessions participants were requested to continue regular practice of the technique and were questioned by the study coordinator regarding their relaxation practice at follow-up BP assessments. The education group submitted weekly logs which monitored the activities they did for fun, activities they enjoyed, food intake, exercise, recent experiences and stresses, and situations that made them angry.

Measures

BP. Patients initially treated for hypertension had their BP monitored after medication withdrawal. Those patients whose DBP was greater than 90 mm Hg and less than 106 mm Hg (phase V DBP) on two occasions separated by 1 week were selected for this study. Similarly patients initially untreated for hypertension had their BP monitored, and were selected based on the same criterion.

BP readings were taken by the study nurse using a random zero mercury sphygmomanometer. For post-treatment and follow-up assessments, the study nurse was "blind" to subject treatment allocation. At the first assessment, the subject's arm circumference was determined and the appropriate cuff was used at all subsequent visits. The cuff was applied to the left arm with the lower edge at least 1 inch above the crease of the elbow. The subject was asked

not to talk during BP assessments. Three BP readings were taken after the subject was seated quietly for 5 minutes and DBP was taken as the average of the second and third of three readings on each occasion. BP assessments took place at entry, end of treatment, 1 month post-treatment, and 3 months follow-up. During study participation, BP assessments were scheduled according to the following criteria: if the subject's average of the second and third DBP was less than 90 mm Hg, a BP assessment was scheduled in 1 month; if the average DBP was 90–105 mm Hg, a BP assessment was done in 2 weeks; if the average DBP was 106–120 mm Hg, an assessment was done in 1 week, but if DBP was still between 106 and 120 mm Hg 1 week later, the subject was withdrawn from the study; and if the average DBP was 120 mm Hg or greater, the subject was withdrawn from the study.

Pre-intervention and Post-intervention stress tests. The pre-intervention assessment was conducted 1 week after the consent form was signed, and prior to randomization. Before administering the stress tests, three DBP readings were taken. If the average of the last two DBPs was 90–105 mm Hg, the procedure was conducted. The post-intervention assessment was conducted 1 month after the completion of the relaxation or education program.

The subject was asked to avoid caffeine and nicotine for 3 hours before the assessments. After he was seated comfortably, a BP cuff was attached to his left arm, and ECG electrodes were attached to his chest. The subject was asked to sit quietly for 20 minutes, and baseline recordings of apical heart rate (HR) and BP were taken at 2-minute intervals during the last 10 minutes. All HR and BP readings throughout the assessment were taken using the Critikon Exercise Monitor, Model 1165 (Critikon, Johnson and Johnson Co., Markham, Ontario, Canada). Immediately after the 10-minute baseline period, three stress tests were administered by the study nurse and the study coordinator. Standardized physical and mental stressors were used which have previously been used in cardiovascular research. Two mental stressors were used: the mental arithmetic test, which requires concentration on mental work, and the reaction time test, which requires attending to sensory events in the environment. The tests were administered in the following order:

Mental Arithmetic Test: The subject was asked a series of 12 timed mental arithmetic questions from the Wechsler Adult Intelligence Scale (23). Questions were asked one by one until the subject failed to correctly answer 4 consecutive questions, at which time the test was stopped. HR and systolic blood pressure (SBP) were measured every 2 minutes.

Steady State Exercise Test: The subject was seated on a calibrated Monark Ergometer, Model 868 (Monark-Crescent AB, Varberg, Sweden). Recordings of HR and BP were taken at 2-minute intervals for 5 minutes. The subject was then instructed to pedal at a workload of 120 kpm (kilopond meters) for 2 minutes while HR and BP were measured. Workload was increased by 120 kpm at 2-minute intervals until the target workload was reached (24). The target workload was based on the subject's age and height (25). Each time the workload was increased, the subject gave a subjective rating of effort using the Borg Perceived Exertion Scale (26). The test was stopped before the target workload was reached if HR exceeded 160, SBP exceeded 220 mm Hg, or the Borg rating reached 7.

Reaction Time Test: The subject was seated facing a reaction time testing device (a modified Type 300 1A Dawe Digital Frequency Meter Counter and Timer, Dawe Instruments, London, England). Recordings of HR and BP were taken at 2-minute intervals for 5 minutes. After this 5-minute rest period, the subject was given two remote controls, one labeled "start" and the other labeled "stop." The subject was asked to press the start button which caused the number on the digital display to change sequentially. A random number was called out and the subject was instructed to freeze the number on the display by pressing the stop button. Immediately after the automatic reset of the counter to zero, the subject restarted the timer by pressing the start button. The total duration of the test was 5 minutes, with displayed numbers changing each second for the first 2.5 minutes and at a speed of 10 per second for the final 2.5 minutes (27). HR and BP were measured every 2 minutes.

End of study assessment. After the BP was measured, the subject was asked to complete the Jenkins Activity Survey (JAS) (28), and the Hassles and Uplifts Scale (29). The subject was then asked if he thought he was taking the active or inactive medication and if he experienced any side effects from the medication. He was questioned regarding lifestyle changes while participating in the study, for example, smoking, exercise, alcohol use, and weight change. The study nurse was also asked whether she thought the subject was taking active or inactive medication.

Self-Report Measures

1. The JAS and the Hassles and Uplifts Scale were completed during the pre-intervention and post-intervention assessments. Married subjects were also given a copy of the JAS for their spouses to complete. Spouses were asked to answer the questions as they pertained to the subject without consulting him about his responses, and to seal the questionnaire in the envelope provided.

2. Treatment expectancy was measured immediately following the pre-intervention assessment by using a seven-item questionnaire developed by the research team. Subjects were asked to estimate the extent to which their BP would be controlled with medication and/or stress management. They were also asked to indicate how helpful stress management would be in helping them cope with high BP, relieving stress, and giving them more control over their lives (30, 31).

3. The State-Trait Anxiety Inventory (32), State-Trait Anger Scale, and Anger Expression Scale (33) were completed during sessions 1 and 8 of the relaxation or education program. In addition, the relaxation group completed the State-Trait Anxiety Inventory during session 4.

RESULTS

Baseline Characteristics

A total of 38 men initially on medication but now off and returned to mild hypertension, and 22 men untreated for mild hypertension met the eligibility criteria. After explanation of the study, 29 (76.3%) of the 38 men initially treated for hypertension, and 18 (81.8%) of the 22 men untreated for hypertension consented to participate in the study. Five of the nine men initially treated for hypertension, whose BP returned to a hypertensive state after drug withdrawal, refused to participate and wanted to resume the medication they were taking previously. Of the remaining four, one was in the process of retiring, one was leaving on an extended holiday, one was going on long-term disability due to knee surgery, and one employee felt he could not participate due to job commitments. The four untreated mild hypertensives refused to participate because they did not want to take medication.

Table 1 summarizes the baseline characteristics of participants averaged within treatment groups at entry. Analysis of variance showed no statistically significant differences among treatment groups with respect to age, SBP, DBP, and weight.

Protocol Deviations

Three participants (6.4%) did not complete the study. Two discontinued study participation shortly after randomization to relaxation and placebo drug (one due to time constraints and one who failed to keep appointments with no explanation), and one was withdrawn from the education and placebo group because two consecutive DBPs at follow-up were greater than 105 mm Hg. In all cases, the last BP available for the subject was used in the end of study analyses.

BP

Table 2 shows mean BP for each group at entry, and mean change in BP immediately following treatment, 1 month post-treatment, and at 3-month follow-up. Ninety-five percent confidence intervals show significant reductions for all treatment groups at each of the follow-up periods except for the reduction in SBP in the relaxation and placebo drug group at 1 month post-treatment. In Table 3, two-way analysis of variance (unweighted means solution) was used to test for treatment group differences. A statistically sig-

TABLE 1. Baseline Characteristics of Study Participants by Treatment Group[a]

Treatment Group	No. of Participants	Age (yrs) Mean (SD)	SBP (mm Hg) Mean (SD)	DBP (mm Hg) Mean (SD)	Weight (lbs.) Mean (SD)
Relaxation, Beta Blocker	11	42.45 (8.24)	144.91 (14.44)	96.59 (3.06)	203 36 (25.20)
Relaxation, Placebo Drug	12	47.50 (9.35)	143.83 (8.57)	95.58 (2.80)	189.17 (22.80)
Education, Beta Blocker	12	46.58 (7.77)	144.58 (13.20)	96.13 (3.63)	205.25 (29.11)
Education, Placebo Drug	12	49.42 (6.84)	148.42 (9.60)	96.67 (3.54)	185.17 (18.67)

[a] None of the differences are statistically significant.

TABLE 2. BP Changes Within the Four Treatment Groups From Entry BP to BPs at End of Treatment, 1 Month Post-Treatment, and 3 Months Follow-up

Treatment group	Entry	End of Treatment		1 Month Post-treatment		3 Months Follow-up	
	Mean SBP & DBP	Mean change in SBP & DBP	95% CI[a]	Mean change in SBP & DBP	95% CI	Mean change in SBP & DBP	95% CI
Relaxation, Beta Blocker (n = 11)	144.91 96.59	−17.18 −17.95	−24.76,− 9.60 −22.31,−13.59	−21.91 −19.14	−28.96,−14.86 −23 34,−14.94	−23.45 −18.23	−28.59,−18.31 −21.44,−15.02
Relaxation, Placebo Drug (n = 12)	143.83 95.58	−7.42 −5.42	−14.16, −.68 −9.20, −1.64	−7.92 −5.75	−16.29, .45 −9.65, −1.85	−10.58 −6.50	−17.28,−3.87 −10.71, −2.29
Education, Beta Blocker (n = 12)	144 58 96.13	−18.67 −14.46	−23.67,−11.67 −19.17, −9.75	−18.33 −14.46	−26.38,−10.28 −19.15, −9.77	−21.00 −12.96	−27.86,−14.14 −17.47, −8.45
Education, Placebo Drug (n = 12)	148.42 96.67	−10.67 −7.00	−16.73, −4.61 −11.33, −2.67	−12.92 −5.50	−16.77, −9.07 −9.20, −1.80	−10.08 −6.67	−16.17, −3.99 −11.69, −1.65

[a] CI = confidence interval.

nificant reduction in SBP and DBP at end of treatment, 1 month post-treatment, and at 3 months follow-up was found for beta blocker when compared to placebo drug as shown in Table 3. Relaxation was not found to be more effective than education in reducing BP. There was no evidence of an interaction between beta blocker and relaxation (end of treatment, SBP: $F(1,43) = 0.067$, $p = 0.797$; DBP, $F(1,43) = 1.39$, $p = 0.245$; 1 month post-treatment, SBP: $F(1,43) = 1.47$, $p = 0.231$; DBP: $F(1,43) = 1.12$, $p = 0.296$; 3 months follow-up, SBP: $F(1,43) = 0.096$, $p = 0.758$; SBP: $F(1,43) = 1.57$, $p = 0.216$.

A secondary analysis was conducted excluding treatment non-compliers defined as those attending less than 50% of the relaxation sessions and/or taking less than 50% of the study medication. This

TABLE 3. Comparison Between Treatment and Control Groups of BP Changes from Entry BP to BPs at End of Treatment, 1 Month Post-Treatment, and 3 Months Follow-up

Assessment		Mean change		Difference		F^a $df = (1,43)$	P^a
		Placebo drug	Beta blocker	Mean difference	95% CI		
End of treatment	SBP	−9.05	−17.96	−8.91	−15.81, −2.01	6.74	0.013*
	DBP	−6.21	−16.13	−9.92	−14.24, −5.60	21.52	0.000*
1 Month post-treatment	SBP	−10.42	−20.04	−9.62	−16.70, −2.54	7.53	0.009*
	DBP	−5.63	−16.70	−11.07	−15.27, −6.87	28.52	0.000*
3 Months follow-up	SBP	−10.33	−22.17	−11 84	−18.15, −5.53	14.32	0.000*
	DBP	−6.59	−15.48	−8.89	−13.21, −6.75	17.28	0.000*
Assessment		Mean change		Difference		F $df = (1,43)$	P
		Education	Relaxation	Mean difference	95% CI		
End of treatment	SBP	−14.67	−12.09	2.58	−4.32, 9.48	.479	0.493
	DBP	−10.73	−14.41	−0.68	−3.02, 3.66	.20	0.657
1 Month Post-treatment	SBP	−15.63	−14.61	1.02	−6.10, 8.14	.044	0.836
	DBP	−9.98	−12.15	−2.17	−6.39, 2.05	1.39	0.245
3 Months follow-up	SBP	−15.54	−16.74	−1.20	−7.05, 4.65	.220	0.641
	DBP	−9.82	−12.11	−2.29	−6.67, 2.09	1.38	0.246

[a] Two-way analysis of variance. The analysis was conducted using the difference between mean entry BP and mean BP at any one of the three follow-up times.
[b] SBP and DBP are in mm Hg.
* Statistically significant.

analysis was based on the results of 40 participants, and yielded results similar to those in the above analysis.

The above analyses were also conducted using analysis of covariance with pre-intervention BP as the covariate. Similar results were obtained in all cases.

Pre-Intervention and Post-Intervention Stress Tests

Two-way analysis of covariance was conducted to detect effects of the two mental stress tests and the exercise test on SBP, DBP, and HR. Mean change in SBP, DBP, and HR at pre-treatment was used as the covariate in their respective analyses. At pre-treatment, during the resting state, and after the mental arithmetic task, mean SBP, DBP, and HR were similar in the treatment groups. The increase in HR during the mental arithmetic task was significantly less in the presence of beta blocker when compared to placebo drug ($F(1,42) = 7.39$, $p = 0.009$), as shown in Table 4. All other results for all stress tests were not significant. There was no evidence of an interaction between beta blocker and relaxation (mental arithmetic, HR: $F(1,42) = 0.379$, $p = 0.541$, SBP: $F(1,42) = 0.518$, $p = 0.476$, DBP: $F(1,42) = 3.37$, $p = 0.074$; steady state exercise, HR: $F(1,42) = 0.99$, $p = 0.031$ (chance finding), SBP: $F(1,42) = 1.69$, $p = 0.201$, DBP: $F(1,42) = 0.055$, $p = 0.815$; reaction time test, HR:

TABLE 4. Comparison Between Treatment and Control Groups of Difference Between Resting and Peak BP and HR for Stress Tests Prior to and After Treatment

Stress Test		Mean Change		Difference			F^c $df = (1,42)$	P^c
		Placebo drug	Beta blocker	Mean Diff	Adj[b] Mean Diff	95% CI Adj Diff		
Mental Arithmetic	SBP	−1.65	−5.52	−3.87	−1.68	−5.36, 2.00	0.848	0.362
	DBP	−2.94	0.80	−1.24	−1.73	−0.18, 3.64	3.34	0.075
	HR	−5.31	−9.85	−4.45	−2.55	−4.45, −0.65	7.39	0.009*
Steady State Exercise	SBP	3.35	−5.22	−8.57	−3.22	−7.58, 1.14	2.29	0 143
	DBP	3.52	3.59	0.07	0.90	−1.30, 3.10	0.68	0.413
	HR	−2.90	9.39	12.29	4.11	−1.69, 9.91	2.06	0.159
Reaction Time Test	SBP	−0.57	−4.50	−3.93	1.20	−3.75, 6.15	0.242	0.626
	DBP	−4.11	−3.48	0.63	1.04	−1.10, 3.18	0.957	0.334
	HR	2.11	4.28	2.17	−0.47	−3.56, 2.62	0.095	0.760
Stress Test		Mean Change		Difference			F $df = (1,42)$	P
		Education	Relaxation	Mean Diff	Adj Mean Diff[a]	95% CI Adj Diff		
Mental Arithmetic	SBP	−2.39	−4.75	−2.36	−1.48	−5.16, 2.20	0.663	0.420
	DBP	−0.25	−1.07	−0 82	−0.92	−2.83, 0.99	0.941	0.338
	HR	−7.42	−7.64	−0.22	1.14	−0.76, 3 04	1.45	0.236
Steady State Exercise	SBP	−2.55	0.93	3.48	−0.97	−5.54, 3.60	0.183	0.671
	DBP	4.84	2.22	−2.62	−1.45	−3.65, 0.75	1.77	0.191
	HR	5.29	.84	−4.45	−3.80	−9.54, 1.94	1.78	0.189
Reaction Time Test	SBP	−4.15	−0.76	3.39	3.31	−1.64, 8.26	1.79	0.188
	DBP	−4.79	−2 76	2.03	0.66	−1.48, 2.80	0.384	0.539
	HR	5.27	0.98	−4.29	0.92	−2.19, 4.08	0.358	0.553

Diff = difference; Adj = adjusted; CI = confidence interval.

[a] The mean change is the difference between the mean change in physiologic response during the stress test prior to treatment and the mean change in physiologic response during the stress test after treatment.

[b] Adjusted mean differences are presented because the analysis conducted was analysis of covariance.

[c] Two-way analysis of covariance with mean change in HR, SBP, or DBP at pretreatment used as the covariates.

* Statistically significant.

$F(1,42) = 1.76$, $p = .191$, SBP: $F(1,42) = 0.237$, $p = 0.629$, DBP: $F(1,42) = 0.016$, $p = 0.889$).

Self-Report Measures

Self-report measures included the JAS, the Hassles and Uplifts scale, the State-Trait Anxiety Scale, the State-Trait Anger Scale, and the Anger Expression Scale. In all cases, two-way analysis of covariance was used to test for treatment group differences using the pre-treatment scores as the covariate. A secondary analysis was conducted excluding non-compliers. In each analysis exclusion of non-compliers did not alter the results. The significant findings are as follows: a significant reduction in Type A behaviors $F(1,41) = 7.31$, $p = 0.009$, and speed and impatient behaviors $F(1,41) = 4.31$, $p = 0.044$, was found at 3 months follow-up for beta

blocker in the presence of relaxation; a significant decrease was found in the trait-anxiety score for beta blocker compared to placebo $F(1,38) = 4.82$, $p = 0.034$; and a significant increase in the anger-in score of the Anger-Expression Scale, meaning an increase of holding in anger, was found for beta blocker in the presence of relaxation $F(1,37) = 4.19$, $p = 0.048$. The significant interactive effect observed at 3 months follow-up for mean number of hassles is felt to be a chance finding due to multiple testing because of the difficulty of interpretation, that is, the mean number of hassles increased for the beta blocker group in the presence of relaxation but decreased for the placebo group in the presence of relaxation $F(1,41) = 0.94$, $p = 0.040$.

Treatment expectancy was also assessed, and a one-way analysis of variance showed that the groups were similar in their responses to each of seven questions on the questionnaire. Further analysis, conducted to determine whether treatment expectation was correlated with change in BP, showed an association between the expectation that BP medication would completely control high BP and reduction in DBP at 1 month post-treatment ($r = 0.261$, $p = 0.04$) and SBP at 3 months follow-up ($r = 0.270$, $p = 0.04$).

At study completion, participants were questioned regarding changes in lifestyle, including smoking, weight change, and diet. No significant changes were reported, nor was weight change noticed by the interviewer.

Medication Compliance

Pill counts conducted at home visits indicated no treatment group differences and good compliance (range of mean percent compliance by treatment group 83.8% to 92.2%). One patient randomized to beta blocker discontinued study medication within the first month of study participation due to side effects.

Relaxation Compliance

Compliance with relaxation was measured by self-reports of relaxation use in terms of daily relaxation logs during 5 weeks of the 8-week treatment program and a verbal response at follow-up BP assessments as to whether or not they practiced the technique. Seven participants (30.4%) used the technique rarely or never and were thus deemed to be noncompliers. When these individuals were excluded from the secondary BP analysis, the results did not change.

Further BP analysis was conducted for the 16 participants who practiced the technique. These 16 subjects were divided into two groups based on frequency of relaxation practice, those practicing the technique 50% or more of the time as noted on the relaxation logs and those practicing the technique less than 50% of the time. Independent t tests were conducted to determine whether the difference between entry and end of treatment BP, and entry and 1 month post-treatment SBP were significantly different in the good compliance ($n = 9$) and fair compliance groups ($n = 7$). In both cases the results were nonsignificant (end of treatment SBP $t(15) = 0.81$, $p = 0.430$; DBP $t(15) = -1.72$, $p = 0.104$; BPs at 1 month post-treatment were virtually identical).

Tension rating before and after the relaxation exercise for the 5-week period was reviewed for the 16 subjects who practiced the technique. The average rat-

ing of tension level before each relaxation practice session was 5.17 (1.63 SEM), as measured on a 10-point scale. The average reduction in tension level from before to after each exercise was 2.20 (0.77 SEM). This indicates an average reduction in tension of 42.6%.

Blindness to Treatment Allocation

The nurse correctly identified the group assignment for 74% of the subjects on beta blocker and 55% of subjects on placebo. The difference in these proportions was not statistically significant (χ^2 (1) = 2.06, $p = 0.151$). Seventy percent of subjects on beta blocker and 57% of subjects on placebo correctly identified their group assignment, a difference which, again, was not statistically significant (χ^2 (1) = 0.241, $p = 0.623$). Blindness of the nurse with respect to relaxation treatment was not evaluated.

DISCUSSION

The findings of this industrial-based trial involving mostly blue collar hypertensives indicate that beta blocker resulted in significant declines in BP, and that relaxation resulted in no greater reduction in pressure than the control procedure, education. This was true for SBP and DBP immediately after treatment, at 1 month post-treatment, and at 3 months follow-up. Furthermore, no significant treatment difference was observed in BP and HR response to mental or physical stressors aside from the main effect of beta blocker on HR during the mental arithmetic test.

The failure to observe a significant difference between relaxation and the control procedure is inconsistent with several studies (2–8). For example, Irvine et al. (6) found that BP reductions were greater in hypertensives receiving relaxation therapy compared to the control procedure, mild exercise. The contradictory findings may be attributed to three differences between the studies: Irvine's subjects had more relaxation practice sessions, her study was clinic-based rather than industrial-based, and intervention took place in 10 sessions and was modelled after Patel's program (2), whereas our relaxation training consisted of 8 sessions as outlined by Bellissimo (19).

Charlesworth et al. (8) investigated the BP lowering effectiveness of stress management at the worksite, and found it superior to the control procedure, BP monitoring. Differences between the study by Charlesworth et al. (8) and our study that could account for the contradictory results include the fact that Charlesworth's subjects were white collar workers, most of whom were on antihypertensive medications. Charlesworth and colleagues also found a correlation between the reported number of relaxation sessions and BP reduction, suggesting that compliance was an important factor, although they did not assess medication compliance.

One could argue that the duration of stress management training in our study was not long enough. However, Chesney et al. (9) compared an industrial-based intervention of 13 individual, 50-minute relaxation training sessions to a control procedure, BP monitoring. Chesney et al. (9) found a significant reduction in BP in both groups but no significant difference between groups.

Our study was also designed to assess the combined effects of relaxation ther-

apy and beta blocker. We found that the BP-lowering effect of the combination was not statistically different from the effect of beta blocker alone. Luborsky et al. (13) similarly compared behavioral and pharmacological treatments and found medication superior to relaxation, exercise therapy, or biofeedback; they also found that combining relaxation with medication resulted in no further lowering in BP. In addition, these investigators found that the subscales of the JAS showed moderate predictive correlations with drop in DBP. This result was not supported in our study.

The mildly hypertensive subjects chosen for this study may not have been the best population on whom to examine the effectiveness of beta blocker and relaxation therapy in combination because the nadolol by itself reduced BP so much that little additional effect could be expected from the combination. It might have been more appropriate to study poor responders to medication to more accurately assess the effectiveness of the combined regimen.

Another study by Jacob et al. (16) compared relaxation therapy with placebo, diuretic, and beta blocker for treatment of mild hypertension. This study found the effect of relaxation therapy on BP to be very modest, with reductions in BP of questionable clinical significance. Furthermore, there was a lack of generalization of the effect to the patients' natural environment. Jacob's conclusion that "relaxation therapy is not the most efficient first treatment for unselected patients with mild hypertension" is consistent with our own study's findings.

The failure to observe a significant main effect of relaxation in this study may be due to the recruitment of a sample with low responsiveness to relaxation. For example, relaxation might be useful for white collar workers who have to face specific tense interpersonal situations. In a blue collar population, however, the stress at work may be constant for pace of activity, noise, heat, monotony, and pollution, none of which are likely to be amenable to relaxation techniques.

Breier and colleagues' (34) psychophysiological study of controllable and uncontrollable stress lends support to this argument. Breier et al. (34) found that exposure to brief uncontrollable aversive stimuli, such as loud noise, resulted in higher self-ratings of helplessness, stress/tension, anxiety, and depression than accrued under conditions of controllable stress. Lack of control over aversive stimuli also produced greater elevation of endocrine and sympathetic nervous system activity.

A French epidemiological study also addresses this issue from a different perspective. Fouriaud et al. (35) found that, not only do unskilled workers have higher smoking and alcohol consumption and lower regular athletic activity, but that there was an association between higher systolic BP and exposure to constant noise and pressure of assembly line work. In the same vein, Matthews et al. (36) found that stressful work conditions correlated with higher DBP in blue collar factory workers. Changing the workplace to give the worker more control in his job and addressing health hazards in the work environment should be a fruitful research area to possibly improve both BP and quality of life of these workers.

It might be questioned whether our sample size was too small to detect a statistically significant reduction in BP. Based on observed standard deviation in DBP and using conventional methods of calculating power (37), our study had an

80% chance of detecting a 7-mm Hg difference in DBP between the groups. This sample size may not have been sufficient to show a smaller but still significant clinical effect from relaxation, even though it was adequate to show a main effect for medication.

The study's failure to find relaxation efficacious for mild hypertension might be the result of our subjects not really learning to relax. It can be argued that our assessment of relaxation level showing an average tension reduction of 42.6% was a subjective one not corroborated by an objective measure. However, given the absence of a gold standard, and given that relaxation is primarily a subjective experience, we believe it is best assessed by structured, self-monitored reports.

Since our assessment of compliance with relaxation practice is based on self-report data which are known to exaggerate the level of compliance (38), it may be that poor compliance resulted in our inability to demonstrate the efficacy of relaxation. Objective measures of compliance exist, such as the "relaxation word of the day" technique (16) or the built-in clock in the tape recorder (39); however, even these methods are not foolproof because a patient may engage in various activities unrelated to relaxation while the tape is playing. Moreover, when data from the seven subjects who were grossly non-compliant with relaxation were excluded from the data analyses, the results were unchanged.

Our compliance data indicate that 16% of subjects were non-compliant with medication and 30% of subjects were non-compliant with relaxation practice. A non-compliance rate of 30% in subjects using relaxation with regular support and monitoring over a 5-month period suggests that relaxation therapy offers no advantage over medication in acceptance for a working class population. It has already been shown in industrial-based studies such asthe one by Fouriaud et al. (35) that compliance with medical treatment for hypertension is significantly lower in unskilled workers. Our data suggest that in a blue collar population, relaxation is unlikely to be an effective therapy for hypertension aside from the question of its efficacy.

The changes in self-report measures in this study are very modest and their clinical significance uncertain except for the predicted main effect of beta blocker on reducing anxiety. Our data reveal only one significant interactive effect in the predicted direction; the interactive effect of beta blocker and relaxation reduced the JAS total score and factor S subscale (speed and impatience) at follow-up. However, the lack of correlation of the drop in JAS score with a drop in BP makes the finding of questionable usefulness. The other interactive effect, an increased anger-in component of the Anger Expression Scale, was not predicted and is countered by lack of difference in anger as measured by the state-trait anger test, suggesting that it is a chance finding.

The failure of mental and physical stress tests to show a significant difference in HR and BP response, except the effect of beta blocker on HR, was unexpected. It is possible that the stressors did not produce sufficient physiological arousal in these subjects to result in significant differences even though the responses were generally quite large. However, this finding is consistent with the study by Irvine et al. (6) and with Holmes' review of experimental evidence for somatic arousal reduction produced by meditation (40). Holmes (40) concluded that within the existing research there was no consistent

evidence that meditation is more effective for reducing somatic arousal than is simple resting.

In summary, this study did not find relaxation more effective than education in the treatment of mildly hypertensive steel workers, but beta blocker was more effective in lowering BP than placebo. The addition of relaxation to a beta blocker did not increase the significant lowering of BP by medication. Relaxation practice did not modify HR and BP response to a mental or a physical stress, but the beta blocker did reduce HR during a mental stress and as well resulted in a significant reduction in anxiety. The interactive effect of the two interventions reduced the JAS score, but the meaning of this finding is unclear since it is uncorrelated with BP drop. Compliance with relaxation practice was not superior to compliance with medication use in this blue collar population. In view of these findings, future research is suggested on an alternative non-pharmacologic approach to lowering BP in the blue collar worker, that of modification of the workplace environment.

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