PRACTICE OBSERVED

Practice Research

Can general practitioners use training in relaxation and management of stress to reduce mild hypertension?

CHANDRA PATEL, MICHAEL MARMOT

Abstract

To see whether general practitioners could effectively carry out training in relaxation and management of stress to reduce mild hypertension a study was carried out with a subsample of phase 2 of the Medical Research Council's treatment of mild hypertension trial.[1] In the main mild hypertension trial patients had been receiving either an active drug or placebo for six years. In phase 2 a subsample of these patients were randomly allocated either to continue or to stop receiving the active drug or placebo. In a further subsample patients were again randomised to receive or not to receive relaxation therapy. This factorial design presented an additional opportunity to assess whether patients controlled with active drugs might have their blood pressure maintained by this behavioural therapy once drug treatment was stopped and to assess whether blood pressure might be further reduced by this therapy in patients who had been under regular medical supervision for as long as six years and who had already received non-pharmacological advice. The therapy was conducted by general practitioners in group sessions once a week for eight weeks. The training in relaxation was accompanied by galvanic skin resistance biofeedback. At one year follow up blood pressure in the relaxation subgroups was either maintained (in the group who had stopped receiving drugs) or reduced further (in the group who had continued receiving drugs and in both placebo groups), while in the control group it had increased in all the subgroups, but particularly in those who had stopped receiving drugs. Differences in changes in blood pressure between the relaxation and control groups were significant. There were five new cardiovascular events, including evidence of myocardial ischaemia in blindly coded electrocardiograms in the control group, compared with one in the treatment group.

General practitioners, if motivated, can successfully apply this technique of training those with mild hypertension in relaxation and management of stress.

Department of Community Medicine, University College and Middlesex Hospital School of Medicine, London WC1E 6EA

CHANDRA PATEL, MD, FRCGP, senior clinical lecturer
MICHAEL MARMOT, MB, MFCM, professor

Correspondence to: Dr Patel.

Introduction

In previous studies we and others have shown that training in relaxation and stress management and their practice in everyday life can lead to a reduction in blood pressure significantly greater than that achieved by increased medical attention, repeated measurements of blood pressure, or other placebo factors.[2,3] In our most recent controlled trial blood pressure reductions were maintained after four years and there was a strong suggestion of a reduction in cardiovascular morbidity ($p<0{\cdot}05$).[4]

These studies have all been carried out in a research setting and have thus not investigated the use of the techniques studied in general; in particular, can primary health care teams effectively carry out such programmes of behaviour modification after a short course of training? We sought answers to this question in the context of two further questions of clinical importance: can patients with mild hypertension receiving long term pharmacotherapy, with its potential disadvantages,[5] stop taking the drugs but have the reduction in blood pressure maintained by relaxation and management of stress, and can blood pressure be reduced further in patients who have been under regular medical surveillance for several years and have already been given placebo tablets and advice to reduce weight, change diet, stop smoking, and increase exercise? To answer these questions we carried out a study using the general practice research framework of the Medical Research Council's treatment of mild hypertension trial.[1]

Patients and methods

All patients had previously taken part in the Medical Research Council's treatment of mild hypertension trial, which was carried out in 192 general practices in Britain and included 17 354 men and women, aged 35-64 at entry, with phase V diastolic blood pressure in the range 90-109 mm Hg. They were treated with active drugs (propranolol or bendrofluazide) or placebos. In the second phase 2765 early entrants who had completed six years of the trial were randomised to continue or discontinue treatment with active drugs or placebos. The last 134 recruits to the second phase, who consented to enter both the second phase and the relaxation trial, were further randomised to receive or not to receive relaxation therapy. We calculated that with such a sample size we had 80% power to detect differences in systolic blood pressure between the groups of 8·5 mm Hg.[4] Participants were randomised by age and sex group. Random numbers were generated by computer, and one of us, who did not know the patients personally, carried out the allocation.

Initially, five practitioners from five practices agreed to take part. In one practice, however, the random assignments were not performed correctly and this particular practice was therefore excluded, leaving 116 patients from four practices included in the study. Five further patients were excluded as they could not be identified in the Medical Research Council's phase 2 trial record.

The entry examination, which was carried out at the end of phase 1 (at the end of six years in the Medical Research Council trial), consisted of a comprehensive history and full medical examination by general practitioners. A 12 lead electrocardiogram, as well as a blood test for cholesterol and estimations of concentrations of uric acid, urea, and electrolytes, was also performed. As the period between this examination and the start of the relaxation trial was likely to be several weeks it was decided in advance that two trained practice nurses would take two blood pressure measurements (within two weeks before randomisation) with a random zero sphygmomanometer to serve as initial blood pressure.

Table I shows the composition and mean blood pressure of the groups. This analysis was restricted to 103 subjects who were examined at one year and who were included in the final analysis. It shows a difference in initial blood pressure between the relaxation and control groups. This surprising finding was investigated thoroughly by comparing initial blood pressures in six ways: including all 134 patients from the five clinics; excluding the entire clinic (18 patients) where some of the patients were not kept in their assigned groups; excluding only those who were not kept in their assigned groups; using blood pressure measurements taken at the end of phase 1 of the trial, several weeks before the start of the relaxation trial, as initial blood pressure (this included only 129 patients as we were unable to trace blood pressure measurements for five subjects); excluding five subjects not examined at the end of phase 1 as well as excluding the entire clinic where some patients were not kept in the assigned group; and, finally, excluding the same as in the fifth comparison but including only those who were examined at one year follow up (shown in table 1). We found that the initial difference between the relaxation and control groups persisted in each comparison.

A general practitioner and research nurse from each participating practice attended a weekend training course and were provided with a training manual, various handouts, and the relaxation and meditation instruction cassette tapes for their patients. The general practitioners were then responsible for conducting the therapy. Figure 1 shows the treatment plan.

TABLE I—*Comparison of groups and mean blood pressure at entry to study**

	Relaxation group (n=49)	Control group (n=54)
M/F	25/24	27/27
Age (yrs):		
35-44	10	10
45-54	15	17
>55	24	24
Treatment:		
Receiving drug treatment	15	16
Stopped drug treatment	17	13
Receiving placebo	9	12
Stopped placebo	8	13
Systolic blood pressure (mean SD)):		
All groups combined	144·9 (14·68)	135·7 (16·44)
Receiving drug treatment	140·9 (12·95)	126·7 (16·93)
Stopped drug treatment	141·2 (17·33)	136·0 (14·37)
Receiving placebo	151·2 (11·01)	136·5 (14·02)
Stopped placebo	152·5 (18·40)	145·6 (15·30)
Diastolic blood pressure (mean (SD)):		
All groups combined	88·6 (7·50)	85·1 (9·67)
Receiving drug treatment	85·3 (7·03)	81·1 (11·16)
Stopped drug treatment	90·4 (6·24)	82·1 (9·10)
Receiving placebo	89·2 (6·84)	89·8 (7·59)
Stopped placebo	90·5 (9·96)	88·8 (7·41)

*Limited to those seen at one year follow up.

Treatment plan

Session 1—Explain treatment plan, biofeedback concept, types of breathing in different states and demonstrate diaphragmatic breathing. Handouts explaining some facts about high blood pressure and breathing exercises and relaxation instruction cassette are distributed. The patients are asked to practise relaxation once a day and if possible twice a day. Questions are answered.

Session 2—The nature of stress and how it may affect health is explained. The importance of learning stress management is pointed out. A film *Understanding Stresses and Strains* made by Walt Disney is shown. The human function curve is explained. Creative imagery and its uses are explained. A handout listing biological, behavioural, and emotional signs of stress is distributed. Questions are answered.

Session 3—How stress response may be analysed and how positive emotions and behaviour may be used to replace harmful or undesirable emotions and behaviour is explained. The how and why of meditation is explained, supported by a handout giving more details on the subject. Questions are answered.

Session 4—Figures and graphs showing beneficial effects of relaxation and meditation from other studies are shown to increase patients' belief in the methods used as well as to increase their motivation to comply with practice. Questions are answered.

Session 5—The ways of integrating relaxation into everyday life are discussed, and the patient is asked to list 10 situations that he or she finds stressful and to practise one breath relaxation either during or before those situations. Management of emotions such as anger, hostility, and aggression is discussed. A handout on how to develop effective communication skills is distributed. Questions are answered.

Session 6—Protective effects of social support, cultural, and traditional aspects of life are pointed out. Questions are answered, and general discussion and supportive relationships within the group are encouraged.

Session 7—The coronary prone personality, including type A behaviour, is discussed. Those who identify themselves as type A are encouraged to change their behaviour. Possible characteristics of resilient behaviour are discussed.

Session 8—The whole course is summarised. General free discussion is encouraged. The importance of regular practice and integration of the new positive behaviour is re-emphasised without giving the impression that life is going to be regimented with do's and don'ts. The emphasis is on making life more fulfilling and enjoyable.

FIG 1—Treatment plan followed by general practitioners and research nurses to train patients in relaxation therapy.

Patients in the treatment group attended once a week for an hour for eight weeks in groups of 10. During the first half hour the general practitioner discussed the topics laid out in fig 1, and in the last half hour the nurse carried out training in breathing exercises, deep muscle relaxation, and simple meditation using the instruction cassette tape. If the general practitioner was not available the nurse discussed the topics.

The training in relaxation was enhanced by a multichannel galvanic skin resistance biofeedback instrument, which was connected to each patient by means of two finger electrodes. A minute amount of electrical current is passed through these electrodes and a sound signal is produced, the pitch and intensity of which depend on the resistance of the skin. The patient hears this on one side of a headphone while listening to the relaxation instructions given through the cassette tape on the other side of the headphone. As he or she relaxes the sound gradually becomes fainter and lower in pitch and then stops. At this point the nurse increases the frequency of the current that reproduces the signal, and the patient has to relax more deeply before he can stop the signal. This task gets harder as the patient becomes better at relaxing.

Each patient was also given a relaxation and meditation instruction cassette tape for daily practice at home. Emphasis was also placed on the gradual integration of relaxation into everyday life. Everyday occurrences such as stopping at a red traffic light or a ringing telephone were used as reminders to take a deep breath and relax. Subjects were asked to make lists of situations stressful to them personally and to make a habit of brief relaxation during or before these activities, which included waiting in a dentist's surgery, speaking in public, and going for an interview.

Follow up examinations consisted of duplicate measurements of blood pressure after eight weeks, three months, and six months and a full medical examination, including an electrocardiogram and blood test after one year.

Because of the differences in initial blood pressure we carried out an analysis of covariance using one year blood pressure measurements, relaxation or control groups, and different subgroups as independent variables. The analysis of covariance assesses the effect of relaxation after adjusting for differences in blood pressure at entry. This model assumes that the effect of relaxation is the same whatever the initial blood pressure. We checked this assumption by testing for an interaction between initial blood pressure and the effect of relaxation. This was not significant for systolic or diastolic blood pressure.

Results

Analysis is restricted to those who were seen at the one year follow up. Changes in systolic and diastolic blood pressure from entry to one year are shown in table II. The overall changes in systolic and diastolic blood pressure in the relaxation group were significantly more favourable than those in the control group. In each subgroup the differences in systolic pressure favoured the relaxation group, as did the differences in diastolic pressure for three of the four subgroups. The expected rise in pressure in those who stopped taking active drugs is seen in the control group.[6] This rise did not occur in the relaxation group. Changes in blood pressure from baseline at each follow up are shown in fig 2.

The results of analysis of covariance are given in table III. As expected, systolic and diastolic blood pressure at one year were significantly related to pressures at entry ($p<0{\cdot}001$). There was a significantly greater lowering of systolic blood pressure, however, in the relaxation group compared with the control group ($p=0{\cdot}007$) after adjusting for blood pressure at entry and drug subgroup. When the effect of blood pressure at entry was taken into account the net drop in systolic blood pressure at one year in the relaxation group (that is, change in the relaxation group compared with change in the control group) was estimated to be 7·3 mm Hg (95% confidence interval 2·0 to 12·6). This effect was independent of the subgroup the patients belonged to as there was no significant interaction between relaxation and drug or placebo subgroups. The net effect of relaxation on diastolic blood pressure at one year was 2·2 mm Hg (−0·7 to 5·2), which was not significant ($p=0{\cdot}131$) after adjusting for blood pressure at entry and drug subgroup.

Mean concentrations of plasma sodium, potassium, urea, uric acid, and

TABLE II—*Mean changes in blood pressure at one year follow up*

	Relaxation group (n=49)	Control group (n=54)	Difference	(95% Confidence interval)	p Value
	Systolic (mm Hg)				
All groups combined	−4·9	+7·1	−12·0	(6·2, 18·0)	0·0001
Receiving drug treatment	−8·4	+3·9	−12·3	(1·1, 23·5)	0·032
Stopped drug treatment	0·0	+13·9	−13·9	(1·7, 26·1)	0·026
Receiving placebo	−7·5	+7·3	−14·9	(−0·9, 30·7)	0·064
Stopped placebo	−6·0	+4·2	−10·2	(0·6, 19·8)	0·039
	Diastolic (mm Hg)				
All groups combined	−1·5	+2·6	−4·1	(0·8, 7·4)	0·015
Receiving drug treatment	−2·6	+4·4	−7·0	(0·6, 13·5)	0·034
Stopped drug treatment	−0·8	+3·8	−4·6	(−2·0, 11·1)	0·167
Receiving placebo	+3·1	−1·1	+4·2	(−11·7, 3·3)	0·257
Stopped placebo	−6·3	+2·5	−8·8	(2·5, 15·1)	0·009

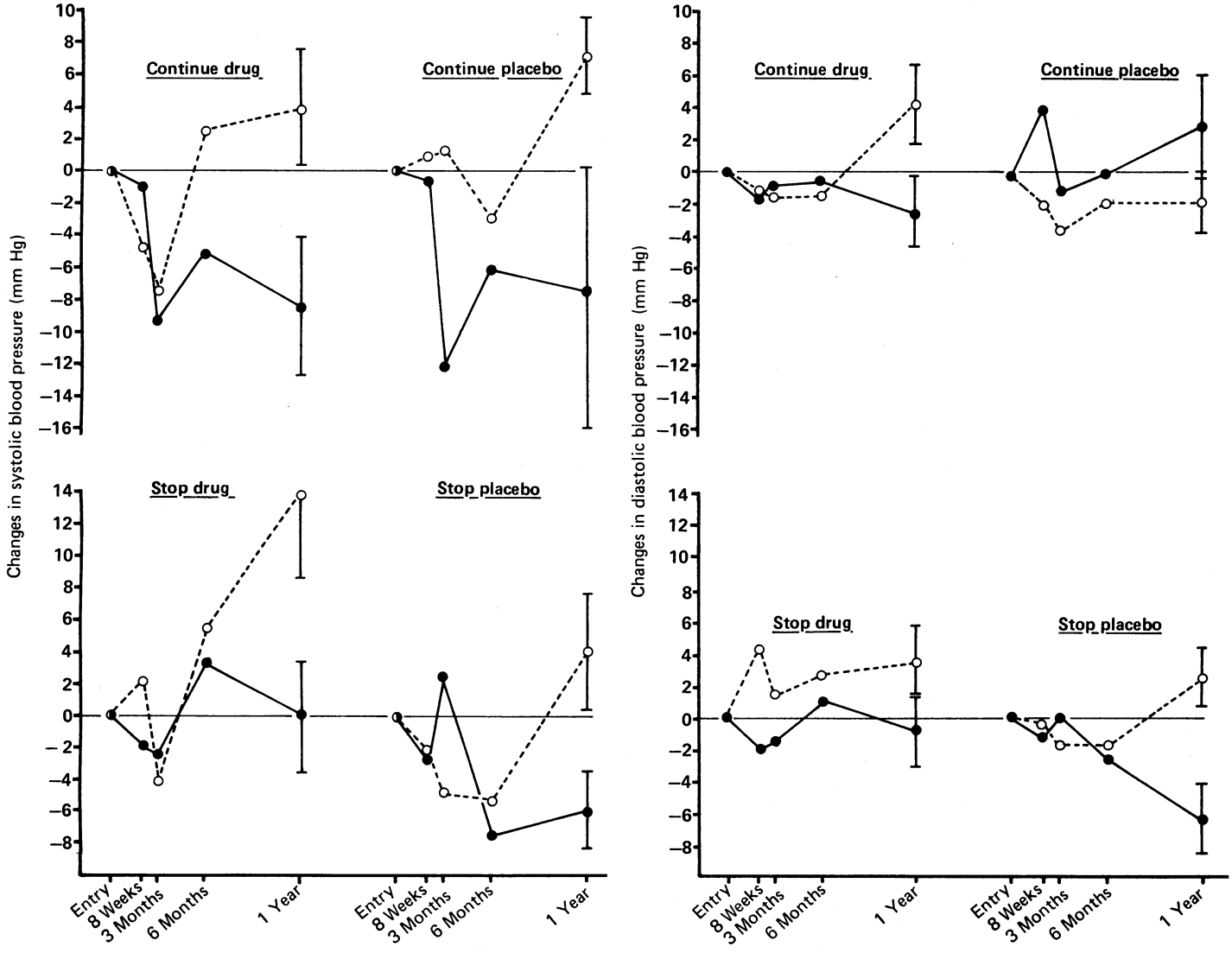

FIG 2—Changes in systolic and diastolic blood pressure from baseline to each follow up examination in relaxation (●——●) and control (○- - -○) subgroups.

TABLE III—*Differences in blood pressure at one year follow up, adjusted by analysis of covariance for differences in blood pressure at entry to study*

	Differences in adjusted systolic blood pressure (p value)	Differences in adjusted diastolic blood pressure (p value)
Between relaxation and control groups, allowing for drug subgroups	−7·3 (0·007)	−2·2 (0·131)
Between drug subgroups receiving placebo groups, allowing for relaxation/control group:		
Receiving drug treatment	−7·7	−3·1
Stopped drug treatment	4·5 (0·003)	−0·7 (0·470)
Stopped placebo	2·0	−1·8
Receiving placebo	0	0

Test for interaction between therapy and drug subgroups p=0·813 (systolic) and p=0·036 (diastolic). This tests whether the effect of relaxation therapy on blood pressure at one year differs significantly among drug subgroups.

TABLE IV—*New cardiovascular events during one year of follow up*

	Relaxation group (n=49)	Control group (n=54)
Reported by practitioner*:		
Angina	0	1
Myocardial infarction	0	1
Stroke	1	0
Through blindly coded electrocardiogram:		
Probable myocardial infarction	0	1
Possible myocardial ischaemia	0	2

*Includes non-responders at one year follow up.
Fisher's exact test: p=0·2383, not significant.

cholesterol were similar in both groups at entry and one year follow up. There was some change, however, in the prevalence of high concentrations of plasma cholesterol. Initially 33% (18 of 54) of those in the control group compared with 35% (17 of 49) in the relaxation group had a serum cholesterol concentration >7·2 mmol/l. At one year 17% (nine of 54) in the control group compared with 12% (six of 49) in the relaxation group had similar cholesterol concentrations.

The development of new cardiovascular events was assessed by history and the results of examination supplied by the practitioners as well as by electrocardiograms analysed blindly using the Minnesota code, and these events are shown in table IV. Among those people followed up at one year there was one new case of angina and three new abnormalities seen on electrocardiograms showing probable or possible myocardial ischaemia in the control group compared with none in the relaxation group. Eight patients were lost to follow up at one year. Of the five in the relaxation group, one had died of carcinoma of the colon, two had moved away, and two did not attend. Of the two who did not attend, one had suffered a stroke three months after treatment with propanolol was stopped in phase 2. Of the three control group patients who were lost to follow up, one was reported to have had a myocardial infarction, one had moved away, and one did not attend. According to our inquiries, patients who had moved away were still alive.

Discussion

The differences in baseline blood pressures among the groups were puzzling. We considered the possibility that the nurse's knowledge of the group to which the patient had been assigned biased her recording of the blood pressure, even though a random zero sphygmomanometer was used. Blood pressure measurements taken at the end of the Medical Research Council's mild hypertension trial (phase 1), however, before the subjects had been allocated to different subgroups for the phase 2 trial, agreed closely with the blood pressures recorded at the beginning of our trial. The differences could not, therefore, have been caused by bias in recording. Bias in the allocation to groups also seems unlikely. The random allocation was not performed in the clinic but centrally, without knowledge of the blood pressures or other characteristics, except age, sex, and the respective general practice. The different blood pressures at baseline were, therefore, presumably due to chance. Even if there is some other explanation the differences in baseline pressures could not account for the favourable results in the relaxation group. After adjustment was made for the initially higher pressures and differences in the composition of the subgroups the drop in systolic blood pressure was still significantly greater in the relaxation group.

Blood pressure in the control subgroup who stopped taking the active drugs showed a similar rise to that seen in the phase 2 study as a whole.[6] The maintenance of blood pressures in the groups who stopped taking active drugs but received relaxation therapy suggests that the effectiveness of this therapy in patients with mild hypertension is comparable to that of the active drugs used in the Medical Research Council trial (non-selective β blocker or thiazide diuretic). The therapy is remarkably safe and may even enhance the quality of life.[7]

A small rise in blood pressure in other control subgroups may be explained partially by the fact that there was an upward trend in blood pressure in phase 2 generally and partially by the fact that the one year follow up blood pressures were taken during the yearly medical examination, while entry blood pressures were taken by research nurses during the two weeks before randomisation when no other examinations were carried out. In the experience of the Medical Research Council team (personal communication), blood pressures at the yearly medical examinations are always higher than at other follow up examinations when only blood pressures are measured. As we are comparing differences in mean changes between groups our results are not greatly affected by similar changes in both groups. The pattern of blood pressure changes shown in fig 2 also suggests that in patients who have been under medical surveillance for several years receiving treatment with active drugs or placebo it may take up to one year for the beneficial effect of relaxation therapy to become apparent.

The number of new cardiovascular events was small, but their pattern was similar to that reported in our previous small study, in which we reported 6:1 events (p<0·05) in control/relaxation groups.[4] This also supports the suggestion that relaxation based behavioural therapy may reduce the incidence of coronary heart disease.

The results show that motivated general practitioners can effectively carry out this therapy for mild hypertension after a short training. As most heart attacks occur among the large number of people with mild to moderate levels of risk factors,[8] general practitioners are in a key position to help prevent coronary heart disease. Relaxation therapy could be a valuable addition to the established practice of advising on other changes in lifestyle.

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